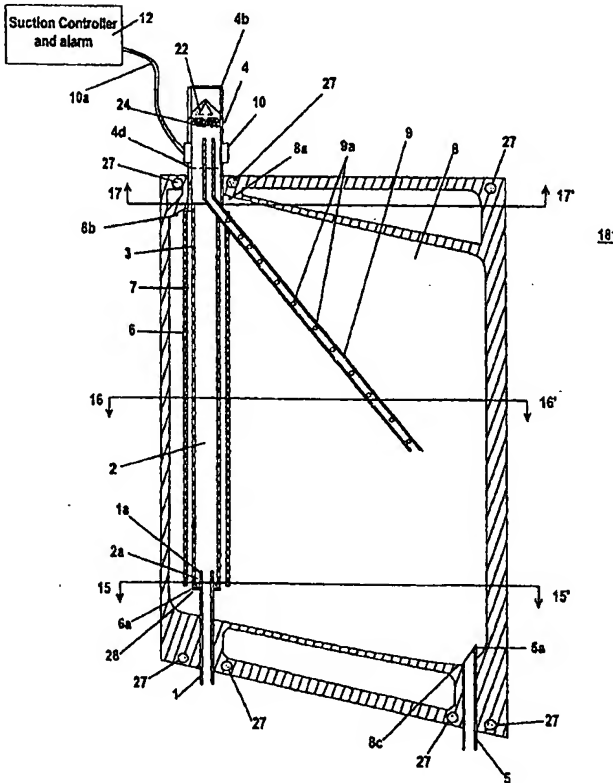


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| <p>(54) Title: AN IMPROVED SOFT SHELL VENOUS RESERVOIR</p> <p>(57) Abstract</p> <p>A soft-shell venous reservoir (1103) that allows vacuum assisted venous drainage (VAVD) using a pump (1114). The soft-shell reservoir is sealed within a, preferably, clear rigid housing. A gas port (4) connected to the space between the bag, and rigid housing is used to adjust the pressure within that space. It allows the user to adjust the "atmospheric" pressure about the external wall of the soft-shell reservoir. Another aspect of the invention improves gas bubble removal. VAVD precludes the use of the safer, soft-shell closed venous reservoir (bag) unless a more expensive, and complicated two pump system is used. VAVD also overcomes flow limitations by applying suction to the hard-shell reservoir thereby increasing the pressure difference between the venous site, and venous reservoir.</p>  |                  |   |

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## AN IMPROVED SOFT SHELL VENOUS RESERVOIR

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of pending application USSN 09/141,960 filed August 28, 1998, the disclosures of this application being incorporated herein by reference thereto.

### FIELD OF THE INVENTION

The invention is a blood reservoir with at least one pliable wall having at least three innovative features. First, the compliant reservoir is sealed within a rigid housing allowing control of the "atmospheric" pressure surrounding the bag, and therefore the pressure at which the bag would collapse. This first invention enables vacuum augmented venous drainage with a collapsible soft-shell reservoir (i.e. venous bag) and is particularly useful for cardiopulmonary bypass. Second, the invention incorporates means that improve gas bubble removal from blood transiting the collapsible reservoir. Third, a reservoir with all ports extending from its top is disclosed, an innovation that provides easy loading/unloading of the reservoir in/out of its holder and simplifies sealing the reservoir in a chamber thereby allowing the aforementioned VAVD.

### DESCRIPTION OF THE PRIOR ART

Blood is routinely pumped outside the body during dialysis, cardiopulmonary bypass, and long term cardiac and/or respiratory support (e.g. extracorporeal membrane oxygenation, ECMO). In general, blood flows from the venous side of the patient to a venous reservoir that is usually maintained at atmospheric pressure. Blood flow from the patient to the reservoir is a function of the resistance of the fluid conduit between patient and reservoir, and the pressure difference between patient and reservoir. When the reservoir is maintained at atmospheric pressure, that pressure difference is the height difference between patient and reservoir; the resulting flow is referred to as gravity drainage. Venous drainage by gravity alone provides inadequate return during procedures such as minimally invasive cardiac surgery and bypass via femoral cannulation. Usually it is the resistance of the venous cannula that limits the flow achievable. Vacuum augmented venous drainage (VAVD) is a technique that overcomes flow limitations by applying suction to the hard shell reservoir thereby increasing the pressure difference between the venous cannulation site and venous reservoir. VAVD allows for a decrease in the inner diameter of the venous line, thereby reducing prime volume, and the use of a smaller cannula, which translates to an easier insertion, a better surgical view and a smaller surgical incision. This method precludes the use of the safer soft-shell closed venous reservoir (venous bag) unless a more expensive and complicated two-pump system is used (see reference 4).

Clinically, a venous bag is used because it provides significant safety features. If the bag empties, it collapses, thereby preventing gross air from being pumped to the patient. It usually has no air-blood interface, and it requires no antifoam agents that can embolize into the blood. A recent study by Schonberger et al (Schonberger JPAM, Everts PAM, and Hoffmann JJ. "Systemic blood activation with open and closed venous reservoirs. *Annals of Thoracic Surgery*, 1995; Vol. 59, pages 1549-55) comparing the hard shell to the bag reservoir found significantly lower blood activation, shed blood loss, crystalloid infusion, and hemolysis, and less donor blood infusion with the bag reservoir. Schonberger's group recommended against routine use of an open (hard shell) venous reservoir system. Currently, a slight negative pressure applied to the venous line (to facilitate blood drainage) using a single pump is possible with less desirable hard shell venous reservoirs. It is impossible to apply negative pressure to current soft-shell reservoirs, but it is possible with the present

invention.

In an open, hard shell reservoir, air escapes by floating to the top of the reservoir. In a bag reservoir, air floats to the top but must be actively eliminated. This can be done manually with a syringe, or more frequently with a roller pump operating slowly so as to continuously pump fluid to the cardiectomy reservoir. With either method, a sudden large volume of air can overwhelm the air removal system and cause disastrous consequences, especially without a vigilant perfusionist. With one preferred embodiment of the present invention, air would be eliminated automatically without a roller pump or intervention by the perfusionist, and priming of the extracorporeal circuit would be facilitated through faster air removal utilizing either a floating ball valve or a hydrophobic membrane. Currently there are devices used in the CPB circuit that incorporate hydrophobic membranes that remove air yet do not allow blood to cross (e.g. Model # AutoVent-SV, Pall Corp Glen Cove NY). Studies with filters used in these applications have shown that the membranes clear air from water almost indefinitely (many days), even if high suction is applied, without reducing gas transfer rate over time. However, when the membrane is exposed to blood, especially when high suction is applied, a film forms on the membrane over time, causing a significant increase in resistance to gas flow. The present invention incorporates designs and means to reduce this problem and extend the life of the membrane when used with blood. Likewise, US Pat. 3,849,071 shows a floating ball within a blood filter that supposed to open a purge port when air enters and close when the blood level rises. However, as described, it is a physical impossibility for the ball to "fall" and open the purge port because, as shown, the weight of the floating ball is insufficient to overcome the force holding the ball against the purge port. With the present invention, the relative weight of the ball, the internal diameter of the purge port, and the suction applied to the purge port are designed to assure that the ball will drop to open the purge port in response to air level in the venous reservoir.

With a soft-shell reservoir (SSR), air may be trapped at the top of the liquid by the collapsed walls of the reservoir, see Fig. 1a and 1aa. US Pat. 4,622,032 illustrates a soft shell reservoir having an inlet tube extending from the bottom half way into the reservoir. This arrangement helps bubbles move up to the top of the extended tubes but the bubbles can still be trapped above said tubes. US Pat. 5,573,526 illustrate the prior art soft-shell reservoir having its gas removal tubes (i.e. 18 and 20 of Fig. 1) extending from the top less 40% of the height of its blood chamber into the reservoir. All other prior art SSR have air removal tubes that are shorter with many having vent tubes that do not extend into the SSR at all (e.g. US Pat. 5,580,349). As figure 1b and 1bb illustrates, a tube extending from the top and into the SSR prevents complete collapse of the pliable walls of the bag thereby forming a pathway for air to move upward. The prior SSR air removal tubes extend less than 40% of the height of the blood chamber and therefore air still may be trapped below said tubes.

Reference 13, sold by Johnson and Johnson (and now by Medtronic) shows a soft shell reservoir with an inline tube extending, along one side of the bag, to the gas purge port at a 45° incline. This design has a rigid fluid path between blood inlet and gas purge port. However, this design is not as conducive to air removal as a vertical fluid path would be. In addition, the tube extending between inlet tube and purge port had an ID of 5/8", or only 25% greater diameter than the inlet tube. Thus, the velocity of the liquid in the column slows to only 64% of the inlet velocity. In another aspect of the present invention, a vertical path is provided from the blood inlet at the bottom of the bag to the gas purge port at the top of the bag, such path limiting the aforementioned problem of trapped air. The vertical path also has a large enough diameter that slows the velocity of the liquid to at least 25%, of the inlet velocity. A lower blood velocity is more conducive to bubble removal.

State of the art soft shell venous reservoirs with a screen are designed such that a large portion of the screen contacts the internal walls of the bag, thereby increasing the resistance to blood flow across the screen, and rendering that portion of the screen ineffective, at least partially. This contact between the screen and the

walls of the bag increases as the volume in the reservoir decreases. In one aspect of the present invention reduces that problem by preventing the external walls of the venous reservoir from contacting the screen.

The indication of blood level in present soft shell venous reservoir is very inaccurate and low level, or air-in-the-reservoir, alarms are not reliable because many are designed for hard shell reservoirs. The present invention provides effective means to alarm at low blood levels and in the soft shell venous reservoir.

Currently, at the end of the bypass procedure, the patient is weaned off the heart lung machine by reducing the bypass flow. This is achieved by partially clamping the venous line and decreasing pump speed. Once off bypass, the blood left in the venous reservoir is gradually pumped back to the venous side of the patient. Another aspect of the invention allows the user to adjust the positive pressure applied to the blood within the venous reservoir. By being able to increase the pressure of the venous reservoir, the user can effectively reduce venous drainage or perfuse the blood back to the patient. This is not possible with current venous reservoir bags and may be dangerous with hard shell reservoirs (i.e., air may be pushed to the patient).

The inventor has also previously described an inline bladder (The Better-Bladder™, see Pending Application s/n 08/474,267), a device with a thin walled, sausage shaped bladder sealed inside a clear, rigid housing. Since the bladder is made from a single piece of tubing, the blood path is smooth with no flow discontinuities. The bladder portion is sealed within the housing that has an access port to the housing space outside the bladder. Because of its thin wall, the enlarged section can easily collapse. Thus, it can serve as an inline reservoir, providing compliance in the venous line to reduce the pressure pulsations at the pump inlet. The Better-Bladder also transmits the blood pressure flowing through it across its thin wall, allowing pump inlet pressure to be measured noninvasively by measuring the gas pressure of the housing via the gas port. The degree of "gravity drainage" is user-adjustable by setting the negative pressure in the Better-Bladder housing. If the suction generated by the venous pump becomes too great, the pump is slowed or stopped by a pump controller. The Better-Bladder does not have a gas purge port or a screen to inhibit gas bubbles. It is also much smaller, having nominal volume of 80ml for adult perfusion as compared to over 1,000ml for a venous reservoir.

Despite users acknowledgement that SSR are safer, hard shell reservoirs are more widely used because they easier to use. For example, it is easier to connect the inlet tubing located at the top of the hard shell reservoir than to the inlet tube of the SSR located at the bottom. Though some SSRs are premounted by the manufacture to a supporting plate (e.g. Cobe see US Pat. 5,693,039) most require multiple hanging hooks for proper support (e.g. Baxter's SSR model # BMR1900 has 3 holes at the top and 4 holes at the bottom), an inconvenience at best, a danger in an emergency. Present mounted SSR do not improve much the tube connection. It would be a clinical advantage to provide a SSR that allows fast mounting and dismounting, and tube connection that are easy or even easier then that of hard shell reservoir. Another requirement for present SSR is the use of a supporting faceplate (e.g. see Fig. 3 of US Pat, 5,573,526). These are used to improve the bubble path from the blood to the top of the reservoir. Such faceplates are again inconvenient, require additional assembly time by the user, and may obstruct the direct approach to the front wall of the bag. The latter is useful when bubbles "stuck" on the wall are to be dislodged. The elimination, or at least the reduced requirement, of a front plate is another desirable attribute.

US Patent 5,823,045 "*Measuring Blood Volume in Soft-Shell Venous Reservoirs (sp.) by Displacement*" illustrates a SSR enclosed in a rigid housing. This invention suggests sealing a SSR within a rigid housing but does not suggest applying vacuum to the fluid surrounding the SSR. In fact, neither the figures nor the specifications mention a port for adjusting the fluid in sealed container 12. Van Driel's patent has some major flaws. The increase in pressure used to monitor volume, causes a decrease in from the patient to the venous reservoir (i.e. gravity drainage.)

The suggestion that tubes connected to the bag are to be "threaded through resilient seals 26 in the bottom of container 12..." also renders '045 clinically irrelevant. If, though not describes as such, container 12 is disposable, then the system as described is too expensive. If, as understood, container 12 is not disposable, then "threading" the tubes would break sterility, and would be very difficult, especially if a seal is required. Further, since the outside diameter of perfusion connectors are larger than the OD of the tubing they connect, it would be impossible to have any of the tubing of the SSR connected to anything until after they have been threaded. In addition, the housing needs to be sufficiently wide for the user to place their hands and thread the inlet and outlet tubes at the bottom of box 12, a major disadvantage that hinders quick setup and increases the likelihood of contamination. This invention has not been reduced to clinical practice.

Since the SSR is sealed in container 12, external means are provided by '045 to "massage" the SSR with "vibrator" 36. In fact, since vibrator 36 is not connected to the wall of the SSR, it can only squeeze the wall rather than the pull and push motions required for vibration. This provides significantly less manipulation ability as compared to direct contact with the bag.

PCT's International Publication Number WO 99/08734 entitled "*System and Method for Minimally Invasive Surgery Vacuum-Assisted Venous Drainage*" illustrates in Fig. 9 a standard SSR ("preferably BMR-800 or BMR-1900") completely sealed in a rigid housing. It is also suggested that the "... a pressure differential between the interior and exterior of the reservoir ..." be maintained. This design is as impractical as that of US Pat. '045. If the bag and rigid housing are assembled and shipped to the end user as a single unit, the unit becomes very expensive and therefore would be used only for VADV cases. The expense arises from a housing required to support a large force. The force can be calculated as  $(\text{Pressure}) \times (\text{Area})$ . Thus, to support a pressure of -250mmHg with a safety factor of 2 for a box that holds a bag like the BMR-1900 (10" high by 12" wide), the force on each faceplate is 1200lb! The inventors did not suggest, nor showed or described, a mechanism for the user to seal the bag in the box. Even if there was, it would be very difficult, time consuming, and, as described with relation to '045, most likely break sterility. And, once sealed it would be impossible for the user to contact the bag.

Both '045 and '08734 illustrate the rigid housing as a rectangular box. A better design to support the large external force due to the large area and vacuum used would be an ellipsoid cross section or at least rounded corners.

Both '045 and '08734 illustrate the great need for designs that allow simple, inexpensive, and quick means to seal and remove the bag from its container even with long tubing or large connectors without affecting its sterility. Simple and quick means to reach the enclosed bag would also be welcomed. The present invention overcomes these clinically non-workable prior art designs.

It is standard practice to place the venous reservoir *above* the oxygenator to assure that the microporous membrane is always under positive pressure. A negative pressure would result in air crossing the membrane and entering the arterial line, a very dangerous situation. When VAVD is used, suction can be applied to the venous reservoir only once the arterial pump is generating a positive pressure in the arterial line. Otherwise, the suction applied to the venous reservoir can draw air across the membrane. A one-way valve at the pump outlet prevents vacuum applied to the venous reservoir from reaching the membrane oxygenator but a one-way valve incorporated into the outlet of the present venous reservoir is preferable. Means to assure that the gas side of the membrane oxygenator is always positive relative to the blood side would also be a major safety feature for all VAVD applications.

#### SUMMARY OF THE INVENTION

The present invention incorporates improved designs for venous reservoirs that provide the benefits of

prior art devices (limiting pump suction using the safer, pliable blood reservoir) while avoiding their disadvantages (air entrapment, inability to utilize VAVD, required vigilance for air removal). Further, its advantages and uniqueness are also enhanced by providing the user with means to adjust the degree of suction applied for venous augmentation and assuring that a greater area of the screen is effective in liquid transport.

Briefly, the present invention in its simplest form consists of a blood reservoir having at least one pliable wall, a blood inlet, a blood outlet, and a gas purge port. In one preferred embodiment, a first structure having tubular cross section and semirigid wall is placed above said inlet thereby providing a first path for undesirable bubbles entering the reservoir to move to the top where they are eliminated via said gas purge port. The first structure preferably has an effective cross section that is larger than the ID of said inlet tube thereby slowing any blood flow and allowing more favorable conditions (longer time, lower drag) for gas bubbles to float upward. The wall of the first structure is sufficiently rigid to prevent collapse of said pliable wall from blocking said first path. In another preferred embodiment the pliable wall of the venous reservoir is sealed externally, forming a pressure chamber external to the venous reservoir. Controlled suction applied to said external chamber is transmitted across said pliable wall thereby controlling the negative pressure of the blood at which said pliable wall moves.

Another preferred embodiment has all the tubes at the top of the SSR. These tubes pass through, sealed within, and physically supported by a rigid disposable supporting plate providing three major advantages. First, the bag is supported by hanging the supporting plate in a supporting fixture, much like the hard shell reservoir. This allows the user to "drop in" the SSR and just as easily remove the SSR from its holder. Second, the supporting plate provides simple sealing means along a single plane, an extremely important feature for simple and secure sealing of the SSR within housing for VAVD applications. Third, by having all the tubes for the bag entering from its top, the bottom of the bag is unhindered and can be placed lower to the floor allowing greater gravity drainage. In addition, because the bag hangs from the top, the weight of the SSR/blood contributes to the seal of the supporting plate against the housing. Design properly, this gravitational force can eliminate, or greatly simplify, any clamping required by other designs.

It is therefore the objective of the present invention to provide an improved venous blood reservoir with at least one pliable wall that provides a path for gas bubbles entering the inlet to move unhindered up to the gas purge port.

A further objective of the present invention is an improved venous blood reservoir, having at least one pliable wall, allowing the user to adjust the negative pressure applied to said pliable wall thereby allowing for augmented venous drainage.

A further objective of the present invention is an improved venous blood reservoir designed to maintain its external wall from contacting the screen material and thereby reducing the resistance to blood flow across the screen.

Yet another objective of the present invention is to incorporate a one way valve at the outlet of the venous reservoir, said valve preventing blood from being sucked into the venous reservoir when pressure at the outlet of the venous reservoir is positive relative to the liquid pressure in the venous reservoir.

Another objective of the present invention is to provide an improved venous blood reservoir with at least one pliable wall that when placed at the pump inlet, provides compliance that reduces pressure fluctuations at said pump inlet.

Another objective of the present invention is to provide an improved venous blood reservoir with at least one pliable wall that when placed at the pump inlet, provides automated means to eliminate air.

Another objective of the present invention is to provide an improved venous blood reservoir with at least one pliable wall and with a relatively large gas purge port, said port providing a more volumetrically

effective gas purge, and one that is less traumatic to the blood.

Another objective of the present invention is to provide automated means to detect air in the venous reservoir and utilize said means to alarm the user or control the suction used to remove air from the venous reservoir.

Another objective of the present invention is to provide the user with a SSR that is simple to use, and easy to load and unload from its holder or from its container.

Another objective of the present invention is to provide the user with a SSR having all its connections above the bag facilitating said connections and allowing a lower placement of the reservoir thus providing greater gravity drainage.

Another objective of the present invention is to utilize gravity to facilitate sealing of the SSR in its VAVD container.

Another objective of the present invention is to utilize the applied suction to facilitate sealing the SSR within its VAVD container.

Another objective of the present invention is to provide a single plane to seal SSR in VAVD container.

Another objective of the present invention is to provide a non-disposable VAVD container that supports at least -100mmHg.

Another objective of the present invention is to provide a disposable cover/holder as part of the SSR for the VAVD container.

Yet another objective of the present invention is to provide a single venous bag that can be used with either standard or with VAVD thus, reducing cost of inventory and simplifying the user's set up.

Another objective of the present invention is to provide a disposable SSR incorporating a structure that facilitates sealing the bag within a non disposable VAVD container, thus reducing cost.

Another objective of the present invention is to provide a SSR incorporating means to prevent the SSR from pulling out of, or twisting within its holder.

Another objective of the present invention is to provide a means to allow suction application to both SSR and cardiotomy independent of the height difference between the two.

Another objective of the present invention is to provide a means to reduce the chance of gas pulled across the microporous membrane when suction is applied to the venous reservoir.

Another objective of the present invention is to provide a VAVD housing having an ellipsoid cross section that can better support a large external force and streamlined to the shape of the SSR.

Another objective of the present invention is to provide a VAVD housing for SSR that does not require the user's hands to be placed within said housing when mounting said SSR in said housing

Other objectives, features and advantages of the present invention will become apparent by reference to the following detailed description of the presently preferred, but nonetheless illustrative, embodiments thereof with reference to the accompanying drawings therein.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a line drawing of the pertinent components of a typical cardiopulmonary bypass (CPB) circuit showing the relative location of the venous reservoir of the present invention.

FIG. 1a is a line drawing of a typical venous reservoir, presently used, illustrating how incoming air bubbles are prevented from reaching the gas exhaust port and are trapped midway in the bag.

FIG. 1aa is a line drawing of a cross section taken of Fig. 1a along line 1a-1a'.

FIG. 1b is a line drawing of a typical venous reservoir according to the present invention, illustrating a pathway provided by channels formed along a tube extended into bag.



FIG. 1bb is a line drawing of a cross section taken of Fig. 1b along line 1b-1b'.

Figure 2a is a line drawing illustrating one preferred embodiment of the present invention where a perforated cylinder is used to keep the flexible walls of the venous reservoir bag away from its screen as well as provide an uninterrupted fluid path between blood inlet and gas exhaust port.

Figure 2b is a line drawing of a cross section taken of Fig. 2a along line 15-15'.

Figure 2c is a line drawing of a cross section taken of Fig. 2a along line 16-16'.

Figure 2cc is an enlarged view of the circled section taken from Fig. 2c.

Figure 2d is a line drawing of a cross section taken of Fig. 2a along line 17-17'.

Figure 2e is a line drawing illustrating the flow of blood and air at the inlet of the venous reservoir shown in Fig. 2a.

Figure 2f is a line drawing illustrating one preferred method to assemble the screen used with the venous reservoir shown in Fig. 2a.

Figure 3a is a line drawing illustrating one preferred sealing scheme of an adult size venous reservoir that allows the use of a universal holder for it and the pediatric venous reservoir shown in Fig. 3b.

Figure 3b is a line drawing illustrating one preferred sealing scheme of a pediatric size venous reservoir that allows the use of a universal holder for it and the adult venous reservoir shown in Fig. 3a.

Figure 4 is a line drawing illustrating one preferred embodiment of the present invention where the venous reservoir is topped with a microporous membrane that allows air, but not blood, to be removed.

Figure 5a is a line drawing illustrating another preferred embodiment of a microporous membrane placed at the top of the venous reservoir allowing air, but not blood, to be removed.

Figure 5b is a line drawing of a cross section taken of Fig. 5a along line b-b'.

Figure 6a is a line drawing illustrating one preferred embodiment of the present invention where air removal is automated by utilizing a floating ball valve.

Figure 6b is a line drawing illustrating another view of the bottom of the ball cage used in Fig. 6a taken along line 23-23'.

Figure 6c is a line drawing illustrating another view of the ball cage used in Fig. 6a taken along line 24-24'.

Figure 6d is a line drawing illustrating another embodiment of the present invention where air removal is automated by utilizing a floating ball valve incorporating two safety features.

Figure 7a is a line drawing illustrating another preferred embodiment of the present invention where a rigid cylinder, incorporated as one external wall of the venous reservoir, maintains the screen wall unhindered and provides an uninterrupted fluid path between blood inlet and gas exhaust port.

Figure 7b is a line drawing of a cross section taken of Fig. 7a along line 25-25'.

Figure 7c illustrates rigid cylinder 72, shown in Fig. 7a, isolated and rotated 90° clockwise.

Figure 7d is an enlarged view of the top, circled section of the venous reservoir shown in Fig. 7a illustrating the slot providing communication for removal of air external to the screen.

Figure 7e is a line drawing of a cross section taken of Fig. 7d taken along line 26-26'.

Figure 7f is a line drawing of a cross section taken of Fig. 7e taken along line 27-27'.

Figure 8a is a line drawing illustrating one preferred embodiment of the present invention where a venous reservoir can be sealed within a rigid housing where suction can be applied to the external flexible walls of said reservoir thereby providing venous augmentation.

Figure 8b is a line drawing of a cross section taken of Fig. 8a along line 28-28'.

Figure 8c is a line drawing of a cross section taken of Fig. 8a along line 29-29' illustrating the rigid bottom cap used with the venous reservoir to seal the bottom of the housing shown in Fig. 8a.

Figure 9a is a line drawing of another preferred embodiment of the present invention wherein the venous reservoir can be sealed within a rigid housing where suction can be applied to the external flexible walls of said reservoir thereby providing venous augmentation.

Figure 9b is a line drawing of a cross section taken of Fig. 9a along line 30-30' showing the bottom seal of the venous reservoir within the housing and door shown in Fig. 9a.

Figure 9c is a line drawing of a cross section taken of Fig. 9a along line 31-31' showing the top seal of the venous reservoir within the housing and door shown in Fig. 9a.

Figure 9d is a line drawing of a cross section taken of Fig. 9a along line 32-32' showing another preferred sealing means incorporated into the inlet tube of the venous reservoir shown in Fig. 9a.

Figure 9e is a line drawing of a cross section taken of Fig. 9d along line 33-33' showing a top view of the means incorporated into the inlet tube of the venous reservoir shown in Fig. 9a.

Figure 9f is a line drawing identical to that shown in Fig. 9d except that this embodiment incorporates a gasket having an indentation to seal about the inlet tube of the reservoir, and a deeper indentation in the housing to support said tube while the venous reservoir is loaded.

Figure 10a is a three dimensional rendering of another preferred embodiment illustrating adaptation of the present invention to other venous reservoir having at least one flexible wall by sealing said flexible wall within a rigid housing such that suction can be applied externally to said flexible wall, thereby providing venous augmentation.

Figure 10b is a line drawing of a longitudinal cross sectional view of Fig. 10a.

Figure 10c is a line drawing of a cross section taken of Fig. 10b along line 10c-10c' showing another view of the venous reservoir within the housing shown in Fig. 10a.

Figure 11 is a line drawing illustrating another embodiment of the present invention where air removal is automated by connecting the gas exhaust port of the venous reservoir to the inlet port of a cardiectomy reservoir, said cardiectomy having negative pressure applied to it.

Figures 12a is a line drawing illustrating another preferred embodiment of the present invention, similar to that shown in Fig. 8a, except that all the tubes entering the bag enter from the bottom and incorporate a disposable cover plate.

Figure 12b is a line drawing of a cross section taken of Fig. 12a along line 112-112'.

Figure 12c is line drawing of a cross section taken of a bottom view of cover 89 of Fig. 12a along line 29-29'.

Figures 13a is a line drawing illustrating one preferred embodiment of the present invention where all the tubes entering the bag enter from the top and are supported by a disposable supporting plate.

Figure 13b is a line drawing of a cross section taken of Fig. 13a along line 131-131'.

Figure 13c is line drawing of a cross section taken of a top view of cover 1389 of Fig. 13a along line 132-132'.

Figure 13d is line drawing of a front view of a SSR shown in Fig. 13a having an outlet section with the outlet tube centered at the bottom and connected to the side wall of the bag.

Figure 13dd is a line drawing of a cross section taken of Fig. 13d along line 133-133'.

Figure 13e is line drawing of a front view of a SSR shown in Fig. 13a having a different outlet section with the outlet tube on the side and connected to the side wall of the bag.

Figure 13ee is a line drawing of a cross section taken of Fig. 13e along line 134-134'.

Figure 13f is line drawing of a preferred embodiment of top cover 1389 shown in Fig 13a and a combination of components designed to reduce the chance of air crossing the into the arterial line by applying controlled suction to the gas side of the oxygenator.

## DETAILED DESCRIPTION OF THE INVENTION

Reference should now be made to the drawings wherein the same reference numerals are used throughout to designate the same or similar parts. It should be noted that the use of cardiopulmonary bypass, as shown in FIG. 1, is for descriptive purposes, and should not be taken as a limitation to the use of the devices described hereinafter. It should also be noted that the term soft shell reservoir, venous bag and bag are used interchangeably.

FIG. 1 is a schematic representation of a system according to the present invention and showing the relative location of the venous reservoir in a typical cardiopulmonary bypass circuit. As shown, tubing 123 inserted at one end by means of a cannula (not shown) in the vena cavae for obtaining venous blood from the heart (not shown) of patient 1102. Tubing 123 is coupled, as an example, to venous reservoir 1103. The blood is drawn from venous reservoir 1103 via tube 135 by roller pump 1104 and pumped through a membrane oxygenator 1105 wherein oxygen is supplied to the blood and carbon dioxide is removed. The blood from the oxygenator is then conducted by means of tubing 157 to arterial filter 1107 and then via tubing 172 and an arterial cannula (not shown) back to the patient. As described in the prior art, the venous blood, here shown coming from the patient's vena cavae, may contain air that must be eliminated before it is pumped back to the patient. This is one of the main functions of the venous reservoir. As shown, air entering venous reservoir 1103 rises to the top of said reservoir where it is removed by suction pump 1114 to cardiotomy reservoir 1115. Roller pump 1104 is usually one of 3 to five pumps composing a heart-lung machine, which part of a the hardware required for cardiopulmonary bypass.

Figures 2a, 2b, 2c, 2d and 2e illustrate line drawings of one preferred embodiment of the present invention. Here, venous blood enters the venous reservoir 1819 via inlet tube 1 and is directed into first inlet chamber 2, shown as a cutaway. First inlet chamber 2 preferably has a circular cross section with its walls formed of fine screen 3 typically having a pore size of  $40\mu$  to  $150\mu$  and having an effective open area that is preferably greater than 40%. It is understood that though lower pore sizes result in higher resistance to blood flow, they prevent smaller bubbles from crossing the screen. It should also be understood that screen 3 is preferably heparin coated, to increase wettability and reduce clot formation. The top of chamber 2 is in fluid communication with gas purge port 4. The bottom of chamber 2 is open and is in fluid communication with inlet tube 1 and, via expandable chamber 8, with outlet tube 5. Preferably outlet tube 5 is located on the opposite side of, and lower than, inlet tube 1. (Bentley patent?)

In one of the preferred embodiment, shown in Fig. 2a, first inlet chamber 2 has a larger inside diameter than inlet tube 1 (e.g. 1.0" v. 0.5"), said larger diameter serves to slow the velocity of the blood (e.g.  $\frac{1}{4}$  the inlet velocity), and thus allow more time for any bubbles to rise to the top where they can be removed. Slowing the blood also reduces the tendency of the flowing blood to carry the bubbles, especially the smaller ones, by reducing the drag on the bubbles by the moving blood. Lower velocity also lowers the tendency of larger bubbles to break into smaller ones; larger bubbles have a higher buoyancy and less of a chance of crossing screen 3 into expandable chamber 8, and flowing out of the bag through outlet tube 5 shown in Fig. 2a. With sufficient pressure across screen 3, the bubbles could cross into chamber 8 and travel to outlet 5 of the reservoir, a very undesirable outcome. To reduce that possibility, inlet chamber 2 is open at the bottom where debubbled blood can exit first inlet chamber 2 at 2a. To improve flow conditions, the outlet of inlet tube 1, 1a, is preferably centered with the centerline of chamber 2, as also shown in Fig. 2b (cross-section 15-15' in Fig. 2a). It should also be obvious that since screen 3 may be flimsy, it may need radial support, as for example internal cage 26, see Fig. 2c (cross section 16-16' in Fig. 2a) and 2f. Screen 3 can be attached to cage 26 by

various means (e.g. insert molding) longitudinally and radially to 26a or 26b and longitudinally to rib 26c, for example by adhesive. This would maximize the ID of first internal chamber 2 to provide a smooth and straight vertical flow path thereby facilitating the upward motion of the bubbles.

With this design, as is the case for present venous reservoir bags (e.g. Bentley, Cobe, Sarns/3M, Minntech) most of the incoming blood would exit via screen 3 across which very few bubbles, if any, cross. However, present venous reservoir bags are made of four layers: the two outside layers being flexible PVC sheets and the two inside layers being a screen (e.g. US Pat. 4,734,269). The screen is usually folded over with the fold being in the center of the venous reservoir bag and its edges sandwiched and sealed along at least two of edges of the two PVC outer layers. This design is simple but it provides no means to keep the internal surface of the external PVC walls from contacting the external wall of the screen. This contact reduces the effective screen area available for blood flow, especially at low blood volumes, causing further problems because more bubbles cross the screen at lower blood volumes. For example, tests conducted with the Cobe venous reservoir bag (Model # VRB, Cobe Lakewood, CO) showed that at a blood flow of 4.0 L/min and an air flow of 750mL/min, the bubble count (size > 50 $\mu$ ) with a blood volume of 750ml in the bag was 35 bubbles/sec as compared to 94 bubbles/sec when the blood volume was 500ml. The Baxter venous reservoir bag (Model # BMR-1900, Baxter/Bentley Irvine, CA) had similar results: the bubble count increased from 69 bubbles/sec to 160 bubbles/sec when the blood volume decreased from 750 to 500ml.

The present invention eliminates the problem of screen to wall contact by introducing means to maintain the wall of the venous reservoir bag away from the screen as well as to maintain a vertical column of blood within first inlet chamber 2. This can be achieved by either incorporating the means into the disposable bag, or by interfacing a disposable bag with a nondisposable holder, the combination providing the aforementioned means. Fig. 2a illustrates one preferred embodiment of the disposable type. Here, a semi rigid cylinder 6 with perforated wall is placed over screen 3 forming second inlet chamber 7 in fluid communication with expandable chamber 8 via said perforations as well as its open bottom at 6a. The perforations can be effectively formed by using a tubular net with, for example 0.030" to 0.100" diameter strands forming a diamond shaped opening, see 6 Fig. 2a, and can be obtained from Nalle Plastics Inc. Austin, TX. The tubular net can be made of polypropylene, polyester, Nylon, or polyethylene. It must possess at least three properties: 1) sufficient stiffness (either by rigidity of the material or thickness of the yarn) and structure to keep walls 18 and 19 (Figures 2b, 2c, 2d) of venous reservoir bag 1819 (Fig. 2a) away from screen 3 thereby maintaining chamber 7; 2) an opening to allow unhindered fluid communication between chamber 7 and expandable chamber 8; and 3) cause no undesired interaction with biological fluids. Tubular net 6 preferably extends vertically from the bottom of venous reservoir 1819 at its inlet to the top of said reservoir and can be attached to the external wall of tube 4 for support. The inlet to cylinder 6, 6a, may extend below screen 3 providing free fluid communication between inlet 1 and expandable chamber 8. With this design, experiments similar to those described for the Cobe and Baxter bags result in a steady bubble count of 60 at bag volumes of 500 and 1000 ml.

Fig. 2e illustrates the blood path of the present invention. Venous blood with some gas bubbles 23 enters the venous reservoir via inlet tube 1. The inertial forces of the blood exiting outlet of tube 1 propel the blood and bubbles upward into first inlet chamber 2. Chamber 2 is preferentially lined up within  $\pm 15^\circ$  of the vertical line. This essentially vertical position, unlike prior art devices, provides the least resistance for gas bubbles to rise up chamber 2 to gas purge port 4 where they are evacuated by suction applied to port 4b.

As shown in Fig. 2a, screen 3 extends to the top of venous reservoir 1819 where it is sealed to gas venting port 4. This seal prevents blood from exiting at the top where it may drag bubbles out of inlet chamber 2 into expandable chamber 8. Should gas volume increase at 4 and displace blood volume at the top of

chamber 2, the gas could cross screen 3 and enter chamber 7 and chamber 8. Because screen wall 3 may get wet again before all the gas at the top of chamber 8 is removed, that gas can be trapped. Purge tube 9 (see Fig. 2a and 2e) is provided to allow gas to be purged from chambers 7 and 8. For that purpose, the topmost entry point of tube 9 into chamber 8 is the highest point in chamber 8 (e.g. point 8a is higher than point 8b). Tube 9 extends from outlet tube 4 into chamber 8, said extension preferably having holes 9a in its wall to provide better fluid communication with chamber 8 along the entire length of tube 9. Holes 9a allows air to enter tube 9 and be evacuated as described before. Other holes may be punched into tube 9 to allow air to be evacuated at any blood level. The smaller diameter of tube 9 and the location of its outlet at the top of venting port 4 reduces the chance of blood flowing (with bubbles) from chamber 2 to chamber 8 via tube 9. The extension of tube 9 into chamber 8 also forms two channels, shown as 9aa in Fig. 2cc, for air to travel along the tube upwards because the tube prohibits the opposite walls of the bag from making complete contact. Channels 9aa increase in size with increasing outside diameter of air removal tube 9 and thicker/stiffer walls 18 and 19 of bag 1819. Fig. 1b and its associated view along 1b-1b', Fig. 1bb, illustrate how the present invention provides air channels. Fig. 1a and its associated view along 1a-1a', 1aa illustrate how prior art shorter air removal tube (e.g. prior art US Pat. # 5,573,526 Fig. 1 tubes 18 and 20) lack such channels. Tube 9 extends downward into blood chamber 8 at least 40% but preferably over 50% of the height blood chamber 8. As well known in the art, tube 9 can alternatively be sealed directly into chamber 8 and external to gas port 4. As shown, tube 9 is exposed to the same suction applied to exhaust tube 4.

With the present invention because, air moves freely to the top of bag 1819 where it can be purged easily. It therefore should be obvious that the degree of suction applied and the blood volume removed in order to purge the gas should be significantly lower than with present devices. The smaller blood volume removed, the lower flow required to remove the gas and the larger ID of the purge line all contribute to significantly lower blood damage. This is especially true when stopcocks, which have very small ID (e.g., 0.062" and sometimes less) and are used with present devices, are eliminated.

The user may not easily determine the presence of bubbles or the blood level in first inlet chamber 2 due to the opacity of the blood and/or screen 3. Yet another innovation provides means to easily ascertain the presence of bubbles by increasing the ID of gas exhaust port 4 to at least 1/4" but preferably 3/8" or greater. Other venous reservoir bags have gas ports of 1/8" ID or smaller, which presents a high resistance to gas and blood flow. The increased port diameter of the present invention increases the ease by which bubbles rise up tube 4 for two reasons. First, gas bubbles move up easier in a liquid filled tube having a diameter larger than the diameter of the bubbles. Second, a larger diameter tube accommodates larger bubbles with greater buoyancy, providing greater upward force on the bubbles relative to the capillary force within a liquid filled tube that inhibits their movement. Thus, by having an exhaust tube with a larger diameter, the user could pull blood up into tube 4. Should air enter first inlet chamber 2, it would travel up and replace the blood in tube 4 causing the visible blood level 4d (see Fig. 2a) in tube 4 to drop, an indication that air entered the venous reservoir and must be removed. It should be understood that the process can be automated by incorporating level detector 10 radial to port 4, said detector 10 connected to a suction controller and/or alarm monitor. Monitor/controller 12 alarms the user to air entering tube 4 and/or starts the required suction applied to the outlet of tube 4, 4b, to remove said air and raise the liquid level. Once the level detector detects the rising liquid, it can stop the alarm and/or stop the suction used to remove the gas from the venous reservoir. Monitor/controller 12 can, for example, control the speed of the pump providing suction. Alternatively, it can open or close the tube providing suction (not shown) by a solenoid actuated tubing clamp.

As shown in Fig. 2a the large diameter of chamber 2 allows more time for the bubbles to rise to the top and causes less turbulence that could hinder the upward motion of the bubbles. Most of the blood preferably

flows from chamber 2 to chamber 7 across screen 3, thereby assuring the upward motion of the bubbles. This preference is enhanced by cylinder 6 maintaining screen 3 free of contact with venous reservoir walls 18 and 19, see Fig. 2c. Typically, if wall screen 3 forms a cylinder with a 1" diameter, then for an 8" high structure, its surface area is  $25\pi$ . This large effective area is available for blood flowing from inlet chamber 2 to expandable chamber 8 and is virtually independent of the blood volume in expandable chamber 8. Annular space 7 formed by cylinder 6 and screen 3 and better seen in Fig. 2c, serves to separate gas from the blood; any bubbles that may have crossed wall 3 can still be buoyed upward to the top of chamber 7 where they can be removed by tube 9. The blood then flows from expandable chamber 8 to outlet port 5. Should air enter chamber 8, it can still float to the top of said chamber and be eliminated via tube 9. Fig. 2cc, which is an enlargement of the circled section shown in Fig. 2c, illustrates how tube 9 forms air channels 9aa, describes in reference to Figures 1b and 1bb, thereby enhancing air removal by keeping walls 18 and 19 slightly apart along the length of tube 9. Thus with this design, there are three chambers for air elimination: chambers 2, 7, and 8.

A major reason a collapsible bag is used as a venous reservoir is to prevent air from being pumped out of the bag and into the patient should the venous reservoir empty. In present bags this is achieved by having the outlet port (5 in Fig. 2a) at the lowermost point of the bag. This can be incorporated into the present invention. Alternatively, the inlet of outlet tube 5, 5a, can be cut on a diagonal (nominal 35° to 65°) with its pointed end protruding into expandable chamber 8 and its low point in line with the periphery of the bag at 8c, as shown in Fig. 2a. Tube 5 should be made of relatively soft material (e.g. 55 Shore A) and have a relatively large ID/wall ratio (e.g.  $0.5"/0.062"=8$ ). Since a larger ID/wall ratio, as well as softer durometer wall, requires a lower pressure difference across the wall of the tube to collapse the tube, then the combination of higher ratio and lower durometer can be used to quantify the ease of said collapse,  $(ID/wall)/durometer$ . Thus, for the above example,  $(0.5"/0.062")/(55) = 0.147$ . This number is significantly higher than that obtained for the outlet tube typically used at the outlet of present venous reservoirs  $(0.5"/0.093")/(65) = 0.082$ . Since the ease of tube collapse is related to  $(ID/wall)^3$ , (see my US Pat. 5,215,450: Innovative Pumping System for Peristaltic Pumps), even a small change in that ratio causes a large change in ease of collapse. Thus, the softer tubing and/or high ID/wall ratio allows collapsing walls 18 and 19 of venous reservoir bag 1819 to gradually, rather than suddenly, impede the flow out of outlet tube 5. Once empty of liquids, the present aspect of the invention provides a looser seal about the outlet as compared to standard bags. Thus, when inlet flow resumes, less volume is needed to open the outlet tube, thereby providing resumption of flow sooner than present venous reservoir bags.

An experiment was conducted to determine the negative pressure developed between the outlet of venous reservoir 1103 and the inlet of pump 1104 when pump 1104 (see Fig. 1) was pumping at 6.0 L/min out of venous reservoir 1103 and the venous flow into the venous reservoir was less than 6.0 L/min. The reservoir was emptied and its outlet collapsed. Also measured was the blood volume required in the venous reservoir to reopen the venous reservoir outlet. Once emptied, the outlet of the Cobe reservoir bag stayed closed until the volume in the bag increased to over 1,400ml. During that time, the pump inlet pressure (measured in line 35 in Fig. 1) decreased to and remained at over -600mmHg. Once the blood volume in the bag reached 1,400ml, sufficient pressure was exerted to expand walls and release the collapsed outlet of the venous reservoir, thereby allowing resumption of blood flow from the venous reservoir to the pump inlet. A similar experiment with the Baxter bag required an increase in blood volume of 400ml before the high negative pressure at the pump inlet (-580mmHg) was relieved and the bag outlet opened up. With the present invention, only 350ml were required to open the venous reservoir outlet and reestablish flow, and the maximum negative pressure was only -400mmHg.

As shown in Fig. 2a, 2b, 2c, 2d, layers 18 and 19 are heat sealed (e.g., by radio frequency welding) by

a double margin along their upper and lower edges, by a relatively wide seal along their right edge and by a narrower seal along their left edge. Anchoring holes (eyelets) 27, used to hang bag 1819, can be formed by punching holes through, and along, the top and bottom of the heat sealed surface. The preferred configuration includes a hole on both sides of inlet tube 1, outlet tube 5, and gas purge tube 4, and in the upper corner of the bag opposite tube 4 to facilitate secure attachment of the bag to the frame, see Fig. 2a.

It should be understood that various sizes of the venous reservoir could be made without necessarily affecting their performance; for example, three popular sizes having capacities of 400, 1200, and 2000 ml. To simplify manufacturing and reduce costs of the hardware, all reservoir sizes can have the same footprint so each size can utilize the same frame. Here, smaller capacity reservoirs have a smaller bag portion and larger peripheral area (Fig. 3). Anchoring holes 21a, 21b, 21c, 21d, 21e, 21f, and 21g used to attach each bag to the frame can be accommodated by corresponding adjustable supporting pins in the frame, for example, as well known in the art.

Figures 7a, 7b, and 7c illustrate another preferred embodiment of the present invention. Here, rigid cylinder 72 replaces perforated cylinder 6, shown in Fig. 2a, to provide annular space 77 as well as to serve as part of the venous reservoir walls. Pliable venous reservoir walls 18 and 19 are sealed to rigid cylinder 72 on both sides of longitudinal slot 72a, said slot better seen in Fig. 7b and 7c (a cross sectional view of cylinder 72 along lines 272 and 272' in Fig. 7a), providing fluid communication between annular space 77 and expandable outlet chamber 8. To reduce stasis and provide smooth blood flow, the incline at the bottom of the rigid cylinder 72, 72d, matches the bottom incline of chamber 8, 8d. Cylinder 72 (Fig 7b) preferentially has longitudinal lips 72b and 72c along both sides of slot 72a, said lips tapering and thinning as they extend outward. These lips serve to seal venous reservoir walls 18 and 19 about slot 72a (e.g., by radio frequency welding) as well as to form a smooth blood flow path from annular space 77 to expandable chamber 8. It should be obvious that cylinder 72 preferentially is made of biocompatible, clear, rigid thermoplastic that can be easily sealed to venous reservoir walls 18 and 19. A good choice would be rigid PVC. It should be obvious that screen 3, gas exhaust port 4, outlet tube 5, and expandable chamber 8 formed by walls 18 and 19 serve the same purpose described for the venous reservoir embodiment shown in Fig. 2a.

Fig. 7d, which is an enlargement of the circled section shown in Fig. 7a, illustrates another preferred embodiment providing a fluid path between chamber 8 and gas exhaust port 74 that allows air removal present in annular space 77 and expandable chamber 8. Here, cylindrical gas port 74 has a notch 74h, at its bottom, also seen in Fig. 7e, which is a view of Fig. 7d taken along cross section 26-26' and Fig. 7f, which is a view of Fig. 7e taken along cross section 27-27'. As shown, the height of notch 74h extends beyond the top of screen cage 26, 26b. The bottom of notch 74h extends onto the highest point of chamber 8, 8a, which also preferentially corresponds to the highest point of screen 3. Thus, notch 74h provides a fluid communication, see arrow 84 in Fig. 7d, between gas exhaust port 74 and chamber 8. Notch 74h replaces the function of tube 9 shown in Fig. 2a.

As described so far, air removal is accomplished as it is by current techniques: suction pump 1114 (see Fig. 1) typically with 1/4" ID tubing is used to remove the gas from the top of the venous reservoir. This arrangement works but requires constant vigilance and intervention by the user to control air removal. Another innovative feature of the present invention is that air can be automatically eliminated from the reservoir with little or no user intervention required. Three preferable designs for the air purge port use a hydrophobic membrane, a floating ball, or controlled suction. All three methods allow air to be removed with very little, or no blood loss. The user would have the option to connect wall suction or one of the sucker pumps as the suction source for the air purge port, preferably having some regulating means to adjust/limit the degree of suction.

Fig. 4 illustrates one preferred embodiment that achieves a large membrane area at the top of the venous reservoir. The design, with a cross section in the shape of an inverted "V" or "U", achieves a large area and provides an inclined surface. Membrane 45 has an inclined surface that facilitates clearing of any blood film off the surface of the membrane. Gravity and wicking should encourage any such film to "peel" off the surface into the blood pool, thereby maintaining the membrane clearer and the gas transfer rate up. Membrane support 425 can be incorporated as the top of a semi-rigid PVC frame formed into a protective "roof". The inside surface of the roof-contacting membrane incorporates ridges 425a, which are in unimpeded fluid communication with gas port 44. Ridges 425a also support membrane 45 and prevent it from deforming due to pressure differences across its wall. The membrane should meet a high gas flow elimination requirement (at least 1 L/min at -100 mmHg). Membranes preferably are made of PTFE (e.g. Durapel™ from Millipore, Bedford, MA) or polypropylene (e.g. Zintex™ from WL Gore, Elkton, MD), preferably having a pore size between 0.45μ and 1.0μ. The small pore provides a sterile barrier.

The membrane is used to remove air automatically from the venous reservoir by applying suction (from the hospital supply) to purge port 44. A hydrophobic microporous membrane 45 prevents the loss of blood 46 from the venous reservoir. One-way valve 422 may be placed at the outlet of gas port 44 to prevent air from entering the reservoir if the reservoir empties and is exposed to the suction generated by pump 4. Membrane 45 has sufficient surface area to allow the removal of the expected volume of air entering the venous reservoir. Studies have shown that membranes that clear air from water can function almost indefinitely (many days) and high suction can be applied without reducing gas transfer rate over time. (However, over time, when the membrane is exposed to blood, especially when high suction is applied, a film overlays the membrane, resulting in a significant increase in resistance to gas flow. When applying lower suction (preferably between -50 and -200mmHg), the transfer rate of gas across the membrane does not decrease as fast as with high suction (possibly due to less plasma penetration into the pores or lower holding force of the film). Therefore, removing air from blood requires a membrane with a larger area. The larger area compensates for the lower suction used to extend the life of the membrane and the lower transfer rates seen with blood as compared to water.)

Another preferred embodiment, shown in Fig. 5a and 5b, utilizes a tubular microporous membrane 55 in fluid communication with purge port 54, said tubular membrane internally supported and sealed to perforated rigid housing 525. Perforated rigid housing 525 allows gas to cross membrane 55 and enter chamber 59 unimpeded. Housing 525 is sealed at the bottom along 525a. Chamber 59, formed by housing 525, is in fluid communication with purge port 54. Annular space 57 is formed by circular membrane 55 and rigid housing 522. Housing 522 is in fluid communication with first inlet chamber 2 shown in Fig. 2a and preferably located on top of chamber 2. Normally annular space 57 is filled with blood. Should air 523 enter line 1 (see Fig. 2a), it would rise up chamber 2, as shown in Fig. 2f, enter annular space 57 (Fig. 5a), cross membrane 53 into chamber 59 (Fig. 5a), cross port 522a of one way valve 522, and be purged via tube 54. Applying suction to tube 54 facilitates air removal by increasing the pressure difference across membrane 55. As with the "roof" design, vertical placement of the tubular membrane 55 facilitates "peeling" of the blood layer of the surface of the membrane, thereby improving long-term gas transfer.

The second preferred method to remove air utilizes a floating ball, which allows air but not blood to be removed through the purge port. As shown in Fig. 6a, port 622a of unidirectional valve 622 providing fluid communication between chamber 67 and gas exhaust port 64, is open as long as air 623 is present in chamber 67. When most of the air has been eliminated, the rising fluid level brings ball 61 to the top of chamber 67, effectively closing port 622a. In this position, any further withdrawal of fluid from the venous reservoir is prevented. When more air enters the reservoir, the blood level falls, ball 61 drops, and the applied suction



removes air 623. Suction may be provided by a wall source or a suction pump, but preferably is controlled for the purpose described below.

There are two forces maintaining ball 61 up against port 622a keeping said port closed: the buoyancy of the ball and the suction force applied at the gas port ( $F_s$ ).  $F_s = (\pi d^2 S)/4$ , where  $d$  is the inside diameter of air port 622a in contact with ball 61, and  $S$  is the negative pressure (suction) applied via gas exhaust port 64 against said ball. The upward force,  $F_s$ , must be less than the weight of the ball so that when the blood level drops, the weight of the ball overcomes  $F_s$  and the ball falls. Cage 68, in general has a larger ID than the OD of ball 61, see 68a in Fig. 6a and 6c, where Fig. 6c is a line drawing illustrating another view of the ball cage used in Fig. 6a taken along line 24-24'. Cage 68 aligns the ball with air port 622a. The bottom of cage 68 narrows down to an ID smaller than the OD of ball 61, see 68b Fig. 6a and 6b, where Fig. 6b is a line drawing illustrating another view of the bottom of the ball cage used in Fig. 6a taken along line 23-23'. The smaller ID 68b serves to retain ball 61 within its chamber 67 and prevents it from falling into the venous reservoir. For this design, for example, ball 61 may be a 1" solid polypropylene ball (specific gravity  $sp = 0.90$ ), or a hollow ball (where  $sp$  is adjustable). Air port seal 622a could, for example, be made of soft silicone and the ID of the air port may be 1/32". To assure a good seal, the surface of the ball should have a fine finish, preferably with a tolerance of 0.001" or better. The applied suction should be low to assure that ball 61 does not "stick" to gas port 622a in the closed position, and to minimize blood damage. For example, a pressure of -50 mmHg can be applied to remove the air. This degree of suction is sufficient to withdraw the air and maintain the liquid column within first and second inlet chambers 2 and 7 when flexible chamber 8 is less than full, see Fig. 2a. To prevent excess suction from being applied, the line between air port 64 and the suction source can include a t-connector 64c with a suction regulating valve 632 attached at the inlet of side port 64c (Fig. 6d). Such valves are commercially available at various cracking pressures and are currently used for IV infusion sets (e.g., NP Medical, Clinton, MA, cost < \$0.25). As well known in the art, a blood trap (not shown) may be incorporated so any blood that may enter the line would not progress to the suction source, and, in fact, excess lost may be returned to the patient. Alternatively, the gas exhaust port 64 may be connected at 64b to Cardiotomy reservoir 15 (see Fig. 1), to which suction is applied. Thus, any blood that may pass the ball valve system would go back to the patient via cardiotomy 15. Safety is paramount. Therefore, side port 64d, having for example a female Luer, in fluid communication with first inlet chamber (e.g., via chamber 67 in Fig. 6d), is placed prior to either the ball or the membrane. Port 64d provides the user means to eliminate incoming air in a fashion similar to that of present devices, in case the membrane or ball malfunctions.

Another preferred method to remove air is a variation of the second method but without the floating ball valve combination. As shown in Fig. 11, gas port 114 of venous reservoir 113 is extended into a "chimney" that connects to cardiotomy reservoir 15, to which suction is applied at 15a. The degree of suction should be sufficient to elevate the blood level in the chimney above the gas purge port 114, even when the expandable chamber 118 is less than full. Thus, any air entering inlet tube 111 would float to the top of first inlet chamber 112 and enter purge port 114. The air would then displace the liquid in chimney 114 and the additional suction would pull the liquid up the chimney to its original level. This system requires that chimney 114 have an ID that facilitates upward movement of air bubbles, even large ones. The length of the chimney needs to be at least equal to the level of the expected liquid when suction is applied and expandable chamber 118 is full. Beyond that height, the outlet of chimney 114b can be connected via 1/4" ID tube to the cardiotomy reservoir. Suction, applied at 15a, can be provided by the wall source, or suction pump 1114 (Fig. 1) connected to cardiotomy reservoir 15, said suction regulated to appropriate levels as well known in the art.

As described in the Description of the Prior Art, improved venous drainage can be achieved by applying some negative pressure on the venous blood. Another aspect of the invention allows the user to apply

suction with a collapsible reservoir. Figures 8a, 8b, and 8c illustrate venous reservoir 772, described in Figures 7a, 7b, and 7c, placed in generally elliptical, clear rigid, housing 88. Housing 88 is open both at its bottom, defined by border 88a, and at its top, defined by border 88b, said borders having sealing gaskets 82 and 81 respectively. Disposable venous reservoir 772 incorporates rigid bottom cap 89, said cap having lip 89a with its inside diameter matching outside diameter of housing 88 to form a seal along gasket 82. Bottom cap 89 also is sealed to inlet tube 1 at 89a and outlet tube 5 at 89b. A similar arrangement is made at the top of venous reservoir 772 where rigid disk 72d is sealed along top gasket 81 of housing 88. Thus, the user would slip chimney 74 of disposable venous reservoir 772 into the bottom of housing 88, push it up and insert it through opening 88d at the top of housing 88. When lined up, rigid disk 72d is pushed against gasket 81 and bottom cap 89 seals against gasket 82. The bottom and top seals are reinforced and maintained by cap 89 held against housing 88 by snaps 88e, 88f, 88g and 88h that lock onto ridge 89d of cap 89. At the end of the case, snaps 88e, 88f, 88g and 88h, each of which is hinged at its midpoint (e.g. see 88i of hinge 88f) are pushed inward, as shown by respective arrows 812 and 811 for snaps 88f and 88e, causing the bottom of said snaps to move outward, see for example 88e' in Fig. 8b, releasing said snaps from locking ridge 89c and allowing the removal of venous reservoir 772.

Chamber 87, formed between venous reservoir 772 and rigid housing 88, communicates via port 88c with vacuum regulator 813b, said regulator used to adjust the degree of suction applied to chamber 87. Gauge 813a can be used to indicate the applied suction. As described before, venous reservoir 772 responds to pressure differences across its walls 18 and 19 (Fig. 8b). Thus, diminished blood flow from patient 1102, see Fig. 1, due to increased resistance to flow (e.g. smaller cannula) can be increased by applying suction to chamber 87. The suction "pulls" walls 18 and 19 outward thereby pulling the blood into the blood chamber. For safety, housing 88 is sized to assure that venous reservoir 772 cannot over-expand beyond defined limits, said limits defined as a volume in blood chamber 8 that would result in a pressure measured at the top of blood chamber 8 being greater than 10mmHg. Thus, as chamber 8 of venous reservoir 772 expands, walls 18 and 19 move towards the walls of housing 88 until they make contact, see 18a and 19a in Fig. 8b. Once contact is made, further outward motion of walls 18 and 19 is limited by rigid housing 88. To facilitate the use of the system, housing 88 incorporates pole clamp 810, said clamp provides a simple connection of said housing to a heart-lung machine. It should be understood that a rigid component, such as rigid cylinder 72, incorporating into venous reservoir 772, see Fig. 7a 8a, is required to facilitate both the introduction of said venous reservoir 772 into housing 88, and the sealing of said reservoir against gasket 81, shown in Fig. 8a. To enhance the ability of the user to see the blood in venous reservoir 772, light 80, shown in Fig. 8b, can be added to the back of housing 88.

Fig. 9a illustrates another embodiment for a nondisposable housing designed to allow venous augmentation with a collapsible venous reservoir. The concept is similar to that shown in Fig. 7a except that the seals and closure mechanism are different. Here, venous reservoir 772 is placed in container 98, said container having a back plate and four walls forming first open box, 98e, which accommodates venous reservoir 772. Container 98 has a matching door 99 having a front plate and four walls forming second box 99e that also accommodates venous reservoir 772. To operate, venous reservoir 772 is placed in first box 98e and door 99 is closed thereby sealing said venous reservoir, along gasket 92, within space 909 formed by first box 98e and second box 99e. It should be understood that for proper function, the venous reservoir is free to expand within the sealed space 909 thus formed. For free expansion of venous reservoir 772, seals of the venous reservoir within container 98 and door 99 are achieved at inlet tube 1, between 92a and 99a (Fig. 9b), gas exhaust port 4, at 92b and 99b (Fig. 9c), and along outlet tube 5, at 92c and 99c (Fig. 9b). When door 99 is closed, the ID of indentations 92a and 99a form a tight seal about the OD of inlet tube 11. . Similarly,

indentations 92c and 99c form a tight seal about the outside of outlet tube 5 (Fig. 9b), and indentations 92b and 99b form a tight seal about the outside of gas exhaust port 4 (Fig. 9c). To assure a tight seal, relievable latches 99d and 99f lock unto ridge 98d, see Figures 9a, 9b and 9c.

To improve the seal along the inlet, outlet and gas exhaust port, each of said tubes preferably incorporates a secondary structure, see sealing structure 1a in Fig. 9d for inlet tube 1. Sealing structure 1a has a flexible wall forming a wings 1aa and 1ab on the side of tube 1, see Fig. 9e and 9d. The wings are tapered, being thickest at the base and thinnest at the tips, see Fig. 9d. For effective sealing, gasket 92 accommodates wing 1aa at thinner section 92aa and wing 1ab at thinner section 92ab, said accommodation providing a seal between container 98 and door 99 along gasket 92. Gasket 92, for example, can be made of a polyurethane sponge, which conform to the shape of said wings, see Fig. 9d. Wing 1a preferably is bonded or welded to tube 1 and is therefore disposed when venous reservoir 772 is disposed. Similar designs can be incorporated into gas exhaust port 4 and outlet tube 5.

Figure 9f illustrates another preferred embodiment for sealing inlet tube 1 between housing 98 and door 99. Here, gasket 93 is attached to door 99, said gasket having indentation 93a to seal about the inlet tube 1 when door 99 is closed against housing 98. This design also incorporates deeper indentation 98a' in the housing, with a closed circumference greater than 225° and an inside diameter that is less than the OD of inlet tube 1. When the venous reservoir is loaded into the housing, flexible inlet tube 1 is pushed into indentation 98a' where it is retained within said indentation by a pressure fit. This allows the user to load purge port 4 and outlet tube 5. It should be obvious that purge port should be loaded first thereby having the venous reservoir hanging from the top while the other two tubes are lined up before door 99 is closed.

Figures 12a, 12b, and 12c illustrate another preferred embodiment that is identical to that described in Fig. 8a, 8b and 8c with the two major exceptions. Gas removal port 74 and its associated seal 72d shown in Fig. 8a are replaced by gas removal tube 124 shown in Fig. 12a. Tube 124 bends and extends to the bottom of bag 772, see Fig. 12a, and exits in the same direction as inlet tube 1 and outlet tube 5 thereby eliminating the need for top seal 72d. Bag 772 in Fig. 8a has its gas removal port 74 extending straight up with its outlet ending above bag 772 and pointing opposite to said inlet and outlet tubing. Having all three tubes of bag 772 extend beyond blood chamber 8 and in one direction and exit along the same plane allows all three tubes to be threaded, preferably during manufacturing, through bottom supporting plate, or cover 89. Thus, as shown in Figures 12a, 12b, and 12c, inlet tube 1 is threaded through cover 89 and is sealed at 89a, outlet tube 5 is threaded through cover 89 and is sealed at 89b, and gas removal 124 is threaded through cover 89 and is sealed at 89e. Having all tubes extend beyond blood chamber sealed within single plate 89 significantly simplifies sealing bag 772 in housing 88, it allows sealing along a single plane of cover 89 against single O-ring 82 of housing 88. It should be obvious that bottom plate 89 could incorporate perfusion connectors as described in reference to supporting plate 1389 in Fig. 13f.

The other innovative design, shown in Figures 12a and 12b but not in Fig. 8a or 8b, incorporates an opening 88k in front wall 88l of housing 88 allowing the user to reach bag 772 without removing the bag from its housing. Reaching bag 772 was the purpose of the external means provided by aforementioned US Pat. '045 to massage the SSR with vibrator 36. The present invention incorporates removable sealing means to front wall 88l of housing 88, such as door 1288, whose outside outline is shown as a dashed line in Figures 12a and 12b. Door 1288 in its neutral state is supported by hinge 1202 hanging at on front wall 88l. The outside perimeter of opening 88k, shown as a dotted line in Figures 12a and 12b, of front wall 88l is surrounded by flexible seal 83, said seal assuring that when door 1288 is closed, it seals opening 88k from atmospheric pressure. To open door 1288, the user would release any negative pressure in closed chamber 87 then open door 1288 by pulling handle 1288a shown in Fig. 12b. Closure of door 1288 against seal 83 can be facilitated

by tilting front wall 88l either by design, or by tilting entire housing 88, thereby allowing gravity to hold door 1288 against wall 88l. Design correctly, using gravity to push door 1288 against seal 83 can eliminate clamps that may be necessary otherwise. Gravity closing would allow hinged door 1288, if it were not secured to rigid housing 88, to also serve as a pressure relief valve should vacuum fail. As well known in the art of doors, mechanisms to maintain door 1288 open, or even temporarily remove the door, can be easily incorporated in the usual manner. To assure that vacuum is not applied accidentally, door closure is preferably designed such a complete seal occurs only when vacuum is applied *and* the user temporarily pushes against the door. The seal formed by the initial pushing force provided by the user, is then maintained once vacuum build within chamber 87.

Figures 13a and 13b illustrate another preferred embodiment of a soft shell reservoir with the very innovative features: top loading of the reservoir into its holder and easy secure sealing of the bag for vacuum assist. Venous bag 1366 is preferably made by RF welding polyvinylchloride or polyurethane film having thickness of 0.015 to 0.020" along perimeter 1310, to form expandable chamber 138 with walls 1318 and 1319. Folded screen 1303 (e.g. Medifab from Tetko Inc. Depew NY, a polyester mesh with a pore size of 105 $\mu$  and a 52% opening) is placed with fold (preferably not creased) 1303a facing downward and sealed along its vertical sides by welding its side edges between walls 1318 and 1319 along periphery 1310. Screen fold 1303a defining the bottom of screen 1303, preferably is placed at least 1/2" from the bottom of blood chamber 138. The top free edges 1303b and 1303c of screen 1303, shown in Fig. 13b, face upward and, at least partially, are not sealed along the top periphery 1310a and therefore an opening into pouch formed by fold 1303a and the two sealed sides of screen 1303. The screen placement defines four sections, within expandable chamber 138. Bottom or outlet section 138a defined as the section of blood chamber between screen fold 1303a and blood outlet tube 1305. Mid or inlet section 138b defined as the section of blood chamber between the top of screen 1303 and its fold 1303a. In inlet section 138b blood is completely surrounded by screen 1303. Top, or bubble removal section 138c, is defined as the section of blood chamber 138 above inlet section 138b, between the top of screen 1303 and sealed top periphery 1310a. Bubble removal section 138c has no screen. The "in-between" section, 138d, is the section between walls 1318 and 1319 and screen 1303. The four sections are in fluid communication with each other.

As shown, four tubes enter bag 1366. Inlet tube 1301 and infusion tube 1306 are in direct fluid communication with inlet section 138b. Air removal tube 1304 is in direct fluid communication with inlet section 138b and air removal section 138c. Outlet tube 1305 is in direct fluid communication with outlet section 138a. Tubes 1301, 1306 and 1304 enter from the top of blood chamber 138, are sealed along top perimeter of sealed section 1310a, pass through air removal section 138c, two screen edges 1303b and 1303c of screen 1303 and into inlet section 138b. All tubes, except outlet tube 1305, preferably have holes along their length positioned in inlet section 138b. Gas removal tube 1304 also has holes, 1304aa, along its length stationed in both air removal section 138c and inlet section 138b.

Inlet tube 1301 preferably enters blood chamber 138 at a top corner of blood chamber 138 and extends to the bottom of inlet section 138b, preferably diagonally to a bottom corner opposite said top corner. Blood enters inlet tube 1301 at its inlet end 1301a in a downward direction, said inlet being above said blood chamber 138 and changes direction as it flows within curved inlet tube 1301. Outlet end 1301d of inlet tube 1301 is preferably sealed, forcing blood out exiting holes 1301b. Exit holes 1301b are preferably located only along the top length of tube 1301 situated in inlet section 138b that faces air removal section 138c, see Fig. 13a. Thus, venous blood enters inlet tube 1301 in a downward flow at inlet 1301a, is diverted from a downward flow to a more horizontal flow and then in an upward direction through exit holes 1301b. The diversion in flow occurs within inlet tube 1301 distal to inlet 1301a. The upward blood flow pushes bubbles towards air

removal section 138c. A venous bag for an adult patient would preferably have inlet tube 1301 have an ID of 0.5" and exit holes 1301b with a diameter of 0.5" or larger.

Blood entering inlet section 138b preferentially flows to outlet section 138a via screen 1303, said screen, once wet, allowing liquid through but retaining bubbles within inlet section 138b. Bubbles are pushed upwards by the direction of the blood exiting holes 1301b and by bounciness. Bubbles motion towards air removal section 138c and then to access holes 1304a of air removal tube 1304, where they are removed, is obstructed when wall 1318 collapses against its opposing wall, as happens with prior art ssr when blood volume is low. With the present ssr, as described in reference to Fig. 2cc and Figures 1b and 1bb, channels are formed along the outside diameter of tubes 1301, 1306, and 1304 providing a pathway for bubbles to move upward to air removal section 138c and on to access holes 1304a of air removal tube 1304. Air removal efficiency is further improved by extending tube 1304, and preferably also infusion tube 1306, from the top of blood chamber 138 downward into inlet section 138b at least 50% of the vertical distance between the top and the bottom of inlet section 138b but preferably over 80% of the height inlet chamber 138b. If no screen is used, than said extension downward from the top of blood chamber 138 is at least 50% of the height of blood chamber 138.

As shown in Fig. 13a, air removal tube 1304 preferably extends in a diagonal direction within blood chamber 138b thereby providing a longer air removal channel than that possible with said tube extending only vertically. Tube 1306 serving as an infusion line, may be closed at its top and just serve as a spacer that provides air bubbles a pathway to air removal section 138c when low blood volume tends to collapse the blood chamber. In fact additional intermediate gas purge tubes (not shown), similar to tubes 1304 and 1306 may be incorporated in a similar manner to provide more numerous air removal channels. Having air channels from the bottom of the screen to the air removal section, not only eliminates the front plate of prior art venous reservoir, but also allows chamber 138 of bag 1366 to take its natural tear drop shape, much like that shown in Fig 12b. The teardrop shape provides a larger area of the screen (the bottom) for blood flow unhindered by contact with the walls of the bag.

To assure that air bubbles can travel along the entire horizontal length of air removal section 138c towards air removal tube 1304, spacer 138cc may be placed along the top of blood chamber 138. Spacer 138cc prevents the flexible wall forming blood chamber 138 from completely collapsing against its opposing wall when the blood chamber is partially empty. As with the aforementioned air channels provided by tube 1304, preventing said complete collapse increases the efficiency of gas from the top of blood chamber 138.

Another innovative design feature requires that the open ends of the all tubes of venous reservoir 1366 be above blood chamber 138. Inlet tube 1301, gas removal tube 1304 and infusion tube 1306 enter blood chamber 138 from its top. Outlet tube 1305 exits outlet blood chamber 138a in a direction that facilitates outlet flow to exit in an upward direction. For example, as shown in Fig. 13a, tube 1305 exits outlet pocket 138aa, the lowest portion of outlet 138a, in a horizontal direction thereby requiring only 90° turn for changing the normally downward outlet flow to the desirable upward flow. Here the venous reservoir also incorporates supporting plate 1389 having a first and second planar surfaces, with said first planar surface facing blood chamber 138. The tubes of venous reservoir can be threaded through, solvent bonded and sealed during manufacturing to supporting plate 1389: inlet tube 1301 at 1389a, outlet tube 1305 at 1389b, gas removal tube 1304 at 1389c, and infusion tube 1306 at 1389d. Supporting plate 1389 can serve to support bag 1366 by dropping it into holder 1388, as is done with prior art hard shell reservoir (e.g. Baxter holder p/n HSRH for hard shell reservoir p/n HSR4000). For this purpose, the perimeter of supporting plate 1389 is preferably larger than the perimeter of venous reservoir 1366.

Inlet 1305a of outlet tube 1305 tube may also be designed to prevent pocket 138aa, shown in Fig 13a,

from prematurely collapsing (i.e. while there is still blood in outlet chamber 138a) and uncollapsing once blood returns to outlet chamber 138a. This is achieved by having the inlet of tube 1305 cut longitudinal to form a scoop-shape whose walls provide the resilience to maintain the walls of bag 1366 of section 138aa apart. A similar design was described in reference the inlet 5a of outlet tube 5 shown in Fig. 2a.

Another advantage of having all the tubes for the SSR entering from its top is that the bottom of the bag is unhindered by tubing and can be placed lower on to the floor thereby allowing greater gravity drainage.

It should be obvious that other designs of SSR 772 shown in Figure 13a can be made without compromising the spirit of the present invention. For example, Fig. 13d is a line drawing of the bottom part of another preferred embodiment of a SSR, SSR 1362. Fig. 13dd is a line drawing of a cross section taken of Fig. 13d along line 133-133'. SSR 1362 is identical to SSR 1366 shown in Figures 13a and 13b except its outlet section 1368a is shaped as a funnel and its outlet tube 1365 enters said outlet section through back wall 1362a via an angled connection. Here, as for outlet 138a of bag 1366, outlet tube 1365 exits outlet section 1368a at lowest point, pocket 1368aa. The angled connection can be made utilizing, for example, a Halkey-Roberts semi rigid connector # 727AC (St. Petersburg, FL) RF welded to wall 1362a and then connecting outlet tube 1365 to said connector. This design with an angle connector eliminates the need for outlet tube 1365 to be bent, as is the case for the design of outlet tube 1305 shown in Fig. 13a. Though not illustrated, it is also possible to have outlet tube 1305 contained within blood chamber 138 and exiting at the top of bag 1366.

Figure 13e is a line drawing of the bottom part of another preferred embodiment of a SSR, SSR 1372. Fig. 13ee is a line drawing of a cross section taken of Fig. 13e along line 134-134'. SSR 1372 is identical to SSR 1366 shown in Figures 13a and 13b except its outlet tube 1375 enters its outlet section 1378a through back wall 1372a via an angled connection. Here, as for outlet 138a of bag 1366, outlet tube 1375 exits outlet section 1378a at lowest point, pocket 1378aa. The angled connection can be made utilizing, for example, a Halkey-Roberts semi rigid connector # 727AC (St. Petersburg, FL) RF welded to wall 1372a and then connecting outlet tube 1375 to said connector. This design with a semi rigid angle connector eliminates the need for outlet tube 1375 to be bent, as is the case for the design of outlet tube 1305 shown in Fig. 13a.

Figures 13a, and 13b also illustrate a line drawing of one preferred embodiment of a SSR holder that in combination with supporting plate 1389 of venous bag 1366 can form a closed housing that can be used for VAVD. Container 1388, can in one embodiment, consists continuous vertical walls (e.g. an extruded ellipsoid tube), a bottom and open top 1388f forming an internal chamber having an effective internal diameter (e.g. for an ellipsoid the effective diameter being a function of the major and minor diameters.) Open top 1388f preferably has a smaller opening than that of container 1388, said opening sized to at least allow venous reservoir 1366 with its blood chamber 138 empty, to be dropped into container 1388. The internal diameter of container 1388 is sized to prevent blood chamber 138 from over extending beyond aforementioned desirable limits. The perimeter of cover 1389 preferably is larger than opening 1388f so as to close said opening 1388f of container 1388 and form sealed chamber 1309.

When positioned properly, supporting plate, or cover, 1389 closes said opening 1388f forming housing 1309. In one embodiment, cover 1389 preferably has two protrusions along its perimeter, 1389e and 1389f, said protrusions forming a channel therebetween accepting open perimeter 1388a of container 1388. This combination lines up cover 1389 and container 1388, provides a better seal, and hinders cover 1389 from sliding off container 1388.

Rim 1388a along the open perimeter of housing 1388 may incorporate sealing gasket 1382 against which cover 1389 can seal when vacuum is applied to chamber 1309. When regulated vacuum is applied, via port 1308 shown in Fig. 13b, SSR 1366 can be used to enhance venous drainage, as described in aforementioned VAVD. For VAVD, the cross section of container 1388 is preferably ellipsoid, a shape that

accommodates the general shape of SSR 1366 and provides mechanical strength. It also serves to line up top of bag 1366 with its supported bottom, as well as preventing cover 1389 from rotating and thereby preventing the bag from twisting. Twisting along the vertical axis is also minimized by guides 1388c and 1388b extending from the bottom of container 1388, accepting bag 1366. Preferably, guides 1388b and 1388c support bag 1366 via outlet tube 1305, which is stiffer than pliable wall 1319 and 1318. Container 1388 preferably should be made from crystal clear, rigid, scratch resistance, tough material such as polycarbonate that can withstand an internal pressure of at least -250mmHg. Since cover 1389 is disposable, it can be made from less expensive material, such as polyvinyl chloride, and it need not be clear or scratch resistance. Cover 1389 required the physical strength to withstand the expected pressure differences across its wall when used for VAVD, preferably supporting a minimum internal pressure of -200mmHg. Structures such as ribs 1389f, shown in Fig. 13a, can be used to reinforce cover 1389. Reducing opening 1388f by extending 1388g shown in Fig 13b, to "just" allow loading of venous reservoir, reduces the area of cover 1389 that is exposed to vacuum and therefore reduces its required strength.

The top loaded SSR 1366, compared to the bottom loaded design shown in Fig. 8b, has significant advantages. SSR 1366 can be easily placed in the housing with one hand. Once placed, it stays in the holder/housing without clamps (e.g. 88g and 88h in Fig. 8a). With top loading/support, the weight (gravity) of the blood in bag 1366 pulls down cover 1389 against seal 1382 rather than pulling away, thereby using gravity, at least partially, to initiate a seal between cover 1389 and container 1388. Also, the support on top and the weight (blood volume) on the bottom tend to "straightens out" bag 1366. Top loading also provides a single flat plane to seal the bag and its associated tubing within housing 1388. This feature is extremely important to assuring simplicity, reliability, and cost effectiveness. Making one of the walls of the of the housing a disposable rather than the entire housing as shown in Fig. 9 of PCT '16893, reduces costs significantly. Further reduction in costs is achieved by making the disposable wall, a wall with a small area (e.g. top or bottom wall). A smaller area requires lower force to support the same pressure difference and therefore allows use of thinner cover.

Top loaded SSR has two additional advantages. First, when placing venous reservoir 1366 into its holder by hanging it by its supporting plate 1389, blood in blood chamber 138 tends to settle at the bottom of blood chamber 138 lowering the center of gravity towards the bottom of the venous reservoir and far below supporting plate 1389. Thus, supported at its top and pulled down by weight of the blood, gravity is used to assist in maintaining the venous reservoir in a vertical position. Second, cover 1389 responds to pressure differences across its wall in a useful manner. Thus, when suction is applied to chamber 1309, cover 1389 pulls tighter against seal 1382, the additional sealing force approximating the product of the area of 1389 exposed to the vacuum applied and the level of vacuum. For example, for a cover 2" wide and 7.5" long, when a suction of -50mmHg (-1psi) the sealing force would be 15lbs. Similarly, should the vacuum fail, and cover 1389 was not secured to ridged housing 1388, a build up of pressure within chamber 1309 would provide a force to open cover 1389 to relief pressure should it rise above atmospheric.

It is obvious that the safety features described with respect to Fig. 8b apply to bag 1366 and housing 1388 shown Fig 13a. For example, housing 1388 is sized to assure that venous reservoir 1366 cannot over-expand beyond defined limits, said limits defined as a volume in blood chamber 138 that would result in a pressure measured at the top of blood chamber 138 of +10mmHg. Should blood chamber 138 of venous reservoir 1366 expand, walls 1318 and 1319 would move outward until they make contact with the vertical walls of housing 1388, as shown for walls 18a and 19a in Fig. 8b. Once contact is made, further expansion of walls 1318 and 1319 is limited by the vertical walls of rigid housing 1388.

For non VAVD applications container 1388 need not be sealed. For example, front wall 1388e of



housing 1388 shown in Fig. 13b, can be minimized or eliminated to allow the user to reach bag 1366 without removing the bag from the holder. This still provides a venous reservoir featuring easy top loading and connections of the inlet tube, outlet tube, and purge port to the extracorporeal circuit made by an end user from the top of the venous reservoir. Top connections are easier to make in the operating room than the side or bottom connections required with prior art soft shell venous reservoirs. It should also be obvious that bag 1366 can incorporate additional tubing (e.g. for cardiotomy return) in a manner similar to that shown for inlet tube 1301 and/or outlet tube 1305. The advantage of top loading being maintained as long as said additions allow top cover 1389 to be used as shown. To simplify changing from a closed housing and open front wall housing, front wall 1388e of housing 1388, can be designed as a removable wall as described in detail in reference to door 1288 of housing 88 in Figures 12a and 12b.

The aforementioned design of SSR incorporating a disposable supporting plate adds little cost compared to the added convenience and shorter set up time making it economical to use the bag for standard or VAVD procedures. This reduces cost of inventory and simplifies the user's set up and learning curve.

It should be emphasized that all the designs for sealing a venous reservoir having at least one flexible wall within a rigid housing for example, as described in reference to Figures 8b, 9b, 10b, 12b, or 13b, allow the introduction of a venous reservoir into a rigid container without compromising the sterility of the blood contacting surfaces of the venous reservoir. As well known in the art, the blood contacting surfaces of a venous reservoir consist of at least the inside walls of the inlet, the outlet, and the air removal tubes, and the blood chamber. Thus, the present invention overcomes one of the major obstacles, though not mentioned as such in the description of the prior art, inherent in prior art SSR intended to be sealed within a housing, see aforementioned US Pat. '045 and PCT '08734.

Cover 1389 may also incorporate tubing connectors 1389aa, 1389bb, 1389cc, and 1389dd, shown in Fig. 13f, that facilitate assembly of bag tubing and eliminate the need for separate tubing connectors. Thus, inlet tube 1301 is sealed (e.g. solvent bonded) to the bottom of inlet connector 1389aa, said inlet connector providing fluid communication between itself and said inlet tubing. Similarly, outlet tube 1305 is sealed to the bottom of outlet connector 1389bb, said outlet connector forming fluid communication between itself and said outlet tubing. To further enhance the functionality of outlet connector 1389bb, unidirectional valve 1305c may be placed within outlet connector 1389bb. One way valve 1305 is a safety feature that prevents back flow from the arterial line, 157 shown in Fig. 1, should arterial pump 1104 stop. Air removal tube 1304 is sealed to the bottom of air removal connector 1389cc, said connector forming fluid communication between itself and said air removal tubing. Like connector 1389bb, air removal connector 1389cc may incorporate unidirectional valve 1304c. This valve assures that air cannot enter the bag via connector 1389cc. Lastly, infusion tube 1306 is sealed (e.g. solvent bonded) to the bottom of infusion connector 1389dd, said infusion connector forming fluid communication between itself and said infusion tubing. An additional advantage of incorporating rigid connectors into cover 1389: they provide physical strength to the cover further preventing buckling under high vacuum.

Fig. 13f also illustrates means that assure the pressure on the gas side 1105c of microporous oxygenator 1105, not fall below that of chamber 1309. This is achieved by applying the same suction to the outlet of gas port of oxygenator 1105 as is applied to chamber 1309 of Fig. 13a. Thus, vacuum is provided by vacuum regulator 813 via tube 818 to three way valve 1391. Three way valve 1391 channels the regulated vacuum to tube 1390a, said tube in fluid communication with chamber 1309, seen in Fig. 13a and 13b, via connector 1308 placed in housing wall 1388, see Fig. 13f. Valve 1391 also channels the regulated vacuum to tube 1390b, said tube in fluid communication with gas side chamber 1105b of oxygenator 1105. Tube 1390b is also in fluid communication with one way valve 1392, caged in structure 1393a having opening 1393b to



atmosphere, said one way valve opening when pressure in tube 1390b exceeds atmospheric pressure. A similar one way valve 1394, is in fluid communication with tube 1390a connecting suction port 1308 of housing 1388 to said three way valve 1391. Valve 1394 opens when the pressure in tube 1390a exceeds atmospheric pressure. Both valves 1392 and 1394 provide safety and assure that, should vacuum, applied to either tube 1390a or 1390b, fail, that the pressure in said tubes not be built but rather exhaust to atmosphere. It is important the valves 1392 and 1394 have very low cracking pressure, preferably below 10mmHg. It is also important that these valves present a low resistance to gas flow, preferably requiring no more than 10mmHg pressure drop at an air flow of 10 L/min. Similarly, vacuum regulator 813, when used to apply suction to oxygenator 1105, should accommodate gas flows exceeding that expected for oxygenator 1105, or 12L/min for adults. Three way valve 1391 preferably allows the user to apply suction to chamber 1309 via tube 1309a but not to oxygenator 1105, apply suction to both chamber 1309 and oxygenator 1105, or not to apply suction to either chamber 1309 or oxygenator 1105.

Applying suction to the gas side of the oxygenator can reduce  $O_2$  transfer rate because the partial pressure of  $O_2$ ,  $pO_2$ , on the gas side is lowered by the percentage decrease in total pressure on the gas side. Thus, when suction of -50mmHg is applied to the gas side, the total pressure is lowered by 50/760 or 7% thereby nominally reducing the  $O_2$  exchange by 7%. Considering that the percent  $O_2$  used in the sweep gas is less than 100%, it is possible to compensate for decreased total pressure by increasing the % of  $O_2$  in the sweep gas. To avoid reduction in  $O_2$  exchange, it is desirable to apply suction to the gas side only when there is no or very low blood flow. Low blood flow can be indicated by low pressure on the blood side. To achieve this desirable result, suction applied to the gas side of the oxygenator is throttled with valve 1391, said valve responding to pressure readings taken of arterial line 157 shown in Fig. 1. For example, when the pressure in line 157 falls below 100mmHg (a pressure indicating low blood flow), a signal is sent to direct valve 1391 to apply suction to gas exhaust line 1390b of oxygenator 1105 shown in Fig. 13f. It should be pointed out that the decrease in  $O_2$  exchange due to suction application on the gas side (i.e. reduction in  $pO_2$ ) is compensated by longer residence time of the blood (lower blood flow). Applying vacuum to the gas side has no adverse affect on  $CO_2$  exchange.

The scope of the invention should not be limited to the aforementioned embodiments. The invention can be extended to other embodiments as illustrated with the venous reservoir having a single flexible wall assigned to Cordis Dow Corp and made by C.R. Bard (US Pat. 4,424,190). Currently, there are no means to apply suction to the venous blood utilizing this Bard venous reservoir. With the present invention, applying suction to this design of a venous reservoir is simple. Figures 10a, a three dimensional view, 10b, a cross sectional view of 103, and 10c, a cross sectional view along lines 10c and 10c' shown in Fig. 10b, all illustrate a modification of the venous reservoir component shown in Fig. 1 of Pat. '190. Blood enters venous reservoir 103 at inlet 101 into chamber 102, said chamber formed by rigid wall 1019 and flexible wall 1018. Flexible wall is sealed to rigid wall 1019 at along periphery 1019a, said seal made by solvent bonding, RF welding, ultrasonic welding or other appropriate method. Air entering expandable blood chamber 102 is extracted via gas exhaust port 104. Gas exhaust port 104 may incorporate an automated gas removal means, as shown for example, utilizing a hydrophobic membrane as described in reference to Fig. 5a. Blood exits via outlet tube 105. For augmented venous return, the present invention adds face plate 108 that seals the external surface of flexible wall 1018 along periphery 108a of face plate 108, forming sealed pressure chamber 107. The seal 108a and seal 1019a therefore can sandwich the free ends of flexible wall 1018 and can be made simultaneously. Gas port 108b is in fluid communication with sealed pressure chamber 107, and is preferably connected to vacuum regulator 813 shown and previously described in reference to Fig. 8a and 12a. Faceplate 108, is preferably clear and rigid such as clear PVC, polycarbonate, polyethylene terephthalate (PET), polyethylene

terephthalate glycol (PETG), polyester, or alike. Faceplate 108 does not have to be biocompatible because it does not contact blood. It should be clear that by incorporating sealing means between faceplate 108 and flexible wall 1018, similar to those described in reference to Fig. 8a, faceplate 108 can be made nondisposable. Whether disposable or not, faceplate 108 forming pressure chamber 107 allows the user to apply suction to chamber 107 via port 108b, said suction transmitted to the blood via flexible wall 1018 thereby providing augmented venous return.

Fig. 10b shows nondisposable cover 108 rests within lip 1019aa of disposable rigid structure 1019 where it is held lightly. When vacuum is applied to suction port 108b of nondisposable cover 108, the user would hold cover 108 against periphery 1019a of structure 1019. Seal material 1082a, located along the periphery of cover 108, is then compressed therebetween forming sealed chamber 107. The suction within chamber 107 would pull disposable structure 1019 and nondisposable cover 108 together. Thus, the pressure difference across faceplate 108 is used for forming a tighter seal and holding cover 108. As described in reference to cover 1389 shown in Fig. 13a, should vacuum fail, any pressure buildup in chamber 107 would push faceplate 108 open to relieve said pressure.

It should be understood that a comprehensive description of each of the applications of the invention is beyond the scope of a patent application and therefore the aforementioned descriptions are given as illustrations and should not be used to limit the intent, spirit, or scope of the invention. With that in mind, I Claim:

1. A venous reservoir for extracorporeal circuits, said reservoir comprising of:
  - (a) an inlet, an outlet, and a gas purge port, and at least one flexible wall, said flexible wall having a blood side and an external side
  - (b) a rigid wall enclosing said external side of said flexible wall, said flexible wall and said rigid housing defining a first pressure chamber, said first pressure chamber having a gas port through which the pressure in said first pressure chamber is controlled, said controlled pressure being transferred across said flexible wall to control the pressure of the blood in said venous reservoir.
2. A blood reservoir with an inlet, an outlet, and gas purge port, wherein said reservoir having flexible walls, said flexible walls enclosed within a rigid housing having an integral gas port, said flexible walls and said rigid housing defining a pressure chamber, said pressure chamber providing compliance to said reservoir, said reservoir containing a liquid having a second pressure is placed at the inlet of an extracorporeal pump, said first pressure transmitted across said flexible walls affecting said second pressure of said liquid in said reservoir.
3. A blood reservoir as claimed in claim 1 or 2, which further includes means for creating an adjustable pressure at said gas port.
4. A blood reservoir in accordance with claim 1 wherein said rigid wall and said flexible wall are fabricated from material having light transmission properties ranging from transparent to translucent.
5. A blood reservoir in accordance with claim 1, said reservoir having a one-way valve at the outlet of said reservoir, said valve preventing retrograde flow of blood.
6. A blood reservoir as claimed in claims 1 and 2, wherein said first adjustable pressure is a negative pressure.
7. A blood reservoir as claimed in claim 6, wherein said negative pressure enhances withdrawal of blood from a patient.
8. A blood reservoir as claimed in claim 1 or 2, wherein said rigid housing is disposable.
9. A blood reservoir as claimed in claim 6, wherein said rigid housing is sized to assure that said flexible walls of said reservoir can not over expand should excess negative pressure be applied.
10. A venous reservoir, said reservoir comprising an inlet, an outlet, and a gas purge port, said reservoir having a flexible wall, said reservoir having a means to prevent the collapse of said wall when the blood pressure in said reservoir decreases below atmospheric pressure.
11. A blood reservoir as claimed in claim 10 wherein said means to prevent the collapse is effective until said blood pressure has reached at least -50mmHg.
12. A blood reservoir as claimed in claim 10 wherein said means to prevent the collapse is effective until said blood pressure has reached at least B100mmHg.
13. A blood reservoir as claimed in claim 10 wherein said means to prevent the collapse is adjustable.
14. A blood reservoir, said reservoir comprising: an inlet, an outlet, and gas purge port, and at least one flexible wall, said reservoir having a first tubular structure within said reservoir, said first tubular structure having a screen wall, a bottom and a top, said bottom of said first tubular structure positioned above said inlet and said top of said first tubular structure in communication with said gas purge port, said first tubular

structure providing an open passageway through said reservoir independent of the volume in said reservoir thereby providing an unimpeded pathway between said inlet and said gas purge port for gas bubbles entering said inlet.

15. A blood reservoir as claimed in claim 14, wherein said screen wall is surrounded by a rigid spacer, said spacer limiting contact of said flexible reservoir walls with said screen wall.
16. A blood reservoir in accordance with claim 15 wherein said rigid spacer maximizes the surface area of said screen available to transfer blood across said screen.
17. A blood reservoir in accordance with claim 14 wherein said screen wall has a pore size between 40\_ and 150\_.
18. A blood reservoir in accordance with claim 14 wherein said screen wall has an effective open area greater than 40%.
19. A blood reservoir in accordance with claim 14 wherein said screen wall is supported vertically and radially with a cage, said cage maintaining an open unimpeded path through said tubular structure.
20. A venous blood reservoir comprising of:
  - a) an inlet tube entering said reservoir
  - b) an outlet tube exiting said reservoir
  - c) at least one flexible wall in contact with the blood
  - d) a gas purge port allowing the removal of gas from said reservoir

Wherein said reservoir has a first means to limit the removal of blood through said gas purge port.

21. A blood reservoir in accordance with claim 20 wherein said first means is a floating ball valve, said ball valve opening to allow air to be removed and closing to prevent blood from being removed.
22. A blood reservoir in accordance with claim 20 wherein said first means is a hydrophobic membrane.
23. A blood reservoir in accordance with claim 22 wherein said hydrophobic membrane is formed into a cylindrical shape having a sealed bottom and an open top, with an external blood/gas facing wall and a means to apply a negative pressure to said open top to remove gas from an interior of said cylindrical shape.
24. A blood reservoir in accordance with claim 23 wherein said means applies a negative pressure between -50 and -200mmHg.
25. A venous blood reservoir comprising of:
  - a) an inlet tube, said inlet tube having a first inside diameter
  - b) an outlet tube
  - c) at least one flexible wall in contact with the blood
  - d) a gas purge port allowing the removal of gas from said reservoir

Wherein said reservoir having a first means to retain a vertical column of blood, said column having a second inside diameter that is at least twice that of said first diameter, said column placed between said inlet and said purge port to provide a low resistance path for air entering said inlet port to move up to said gas purge port.

26. A blood reservoir in accordance with claim 25 wherein reservoir includes a means to apply suction to said gas port to maintain a liquid column equivalent to the vertical distance between said gas port and a liquid level in said reservoir.

27. A blood reservoir in accordance with claim 25 wherein the ID of said gas purge port is at least 0.25", but preferably 3/8" or greater, said diameter increasing the relative buoyancy of bubbles with respect to a surface effect exerted by an inner wall of said port.
28. A blood reservoir in accordance with claim 25 wherein said larger diameter allows gas bubbles to travel up and replace blood in said gas purge port causing a drop in blood level, said drop resulting in a color change, said color change used as a level indicator of blood in said reservoir.
29. A blood reservoir in accordance with claim 28 wherein said level indicator is monitored electronically by a monitor said monitor alarming the user when said blood level drops below an acceptable level.
30. A blood reservoir in accordance with claim 28 wherein said level indicator is monitored electronically by a monitor communicating with a controller, said controller controlling a suction source such that said suction source is normally off unless said blood level drops below said acceptable levels.
31. A suction controller as claimed in claim 30 wherein said controller controls the speed of a suction pump.
32. A suction controller as claimed in claim 30 wherein said controller controls a solenoid actuated tubing clamp said clamp closing/opening a tube that provides suction to said purge port.
33. A venous reservoir, said reservoir comprising:
- a) an inlet, an outlet, a single gas purge port, first and second walls, with at least one of said walls being flexible, and a structure having a screened wall;
  - b) an inlet chamber defined as an internal space formed within said structure;
  - c) an outlet chamber defined as a space external to said structure;
- with said single gas purge port having two fluid paths, a first path to said inlet chamber and a second path to said outlet chamber, such that said single port provides air removal from both sides of said screen.
34. A blood reservoir in accordance with claim 33 wherein said gas purge port is located at the highest point in each of said chambers.
35. A venous reservoir in accordance with claim 33 which further includes a perforated tube in fluid communication with said gas purge port, said perforated tube extending into said outlet chamber, effective to keeping said first and second walls apart at least 40% below said gas purge port thereby providing a fluid path for gas bubbles from said outlet chamber to said gas purge port.
36. A venous reservoir in accordance with claim 33 that further incorporates a one way valve at the outlet of said gas purge port, said one way valve preventing gas from being sucked into the reservoir when pressure in the reservoir is negative relative to atmospheric pressure.
37. A venous reservoir, said reservoir comprising:
- a) an inlet, an outlet, a single gas purge port, first and second walls, with at least one of said walls being flexible, and a structure having a screened wall;
  - b) an inlet chamber defined as an internal space formed within said structure;
  - c) an outlet chamber defined as a space external to said structure;
- Where said outlet tube extends into said outlet chamber, said outlet tube having an ID, a wall thickness and a Shore A hardness where the product of said ID divided by said wall thickness and further divided by said Shore A hardness is 0.1 or greater.
38. A venous reservoir in accordance with claim 37 where the inlet of said outlet tube located in said outlet chamber is diagonally cut.
39. A blood reservoir comprising of:

- a) an inlet tube, said inlet tube having a first diameter
- b) an outlet tube
- c) at least one flexible wall in contact with the blood
- d) a gas purge port allowing the removal of gas from said reservoir

Wherein said reservoir having a first means to retain a vertical column of blood, said column having a second diameter that is larger than said first diameter, said column placed between said inlet and said purge port to provide a low resistance path for air entering said inlet port to move up to said gas purge port, said larger second diameter providing a liquid path with a velocity that is at least three times slower than the fluid velocity in said inlet.

40. A venous reservoir for extracorporeal circuits, said venous reservoir comprising:
  - (a) at least two walls, at least one of said walls being flexible, said walls having a first perimeter, said walls sealed along said first perimeter to form a blood chamber, said chamber having a top and a bottom;
  - (b) an inlet tube having an inlet and an outlet communicating between said extracorporeal circuit and said blood chamber, said inlet tube entering the blood chamber from the top of said blood chamber, and the outlet of said inlet tube ending in said blood chamber;
  - (c) an outlet tube communicating between said blood chamber and said extracorporeal circuit, said outlet tube having an inlet and an outlet, said outlet tube extending from the bottom of said blood chamber to said extracorporeal circuit; and
  - (d) a gas purge tube allowing the removal of gas from said blood chamber.
41. A disposable venous reservoir as claimed in claim 40 wherein said disposable reservoir further includes a screen positioned across the blood flow path between the outlet of said inlet tube and the inlet of said outlet tube, said screen having a pore size of between 40 microns to 150 microns.
42. A venous reservoir as claimed in claim 40 wherein said inlet tube enters a first top corner at said top of said chamber and the outlet of said inlet tube positioned in said chamber diagonally across said chamber from said first top corner.
43. A venous reservoir as claimed in claim 40 wherein said inlet tube extends into said blood chamber and diverts the direction of blood flow, said blood flowing in a first downward direction as it enters the inlet of said inlet tube, said blood flow diverted from said first downward direction to a second direction, said diversion occurring within said inlet tube distal to the inlet of said inlet tube.
44. A venous reservoir as claimed in claim 40 wherein said outlet tube exits from the bottom of said blood chamber and directs blood flow in said outlet tube in an upward direction.
45. A venous reservoir as claimed in claim 40 wherein further said outlet tube exits from the bottom of said blood chamber in a horizontal direction.
46. A venous reservoir as claimed in claim 40 wherein the inlet of said inlet tube, the outlet of said outlet tube, and said gas purge tube of said reservoir extend through the same plane.
47. A venous reservoir as claimed in claim 46 wherein said plane is essentially horizontal.
48. A venous reservoir as claimed in claim 46 wherein said plane is above said blood chamber.
49. A venous reservoir as claimed in claim 40 wherein blood in said extracorporeal circuit enters said blood chamber via said inlet tube and exits via said outlet tube, said outlet tube receiving blood flowing downwardly within said blood chamber and changing to an upward direction within said outlet tube.

50. A venous reservoir as claimed in claim 40 which further incorporates a supporting plate having a first and a second planar surface, with said first planar surface facing said blood chamber, the inlet of said inlet tube, the outlet of said outlet tube, and said gas purge tube being sealed to and supported by said supporting plate, and exiting through said second planar surface of said supporting plate.
51. A venous reservoir for extracorporeal circuits as claimed in claim 50 which further includes a venous reservoir holder, said venous reservoir holder supporting said supporting plate above said blood chamber when said blood chamber is placed within said reservoir holder.
52. A venous reservoir for extracorporeal circuits as claimed in claim 51 wherein gravity is utilized to assist in maintaining said venous reservoir in a vertical position.
53. A venous reservoir for extracorporeal circuits as claimed in claim 51 wherein said venous reservoir holder further provides a structure that prevents said venous reservoir from expanding beyond defined limits.
54. A venous reservoir for extracorporeal circuits as claimed in claim 51, wherein said venous reservoir may be hung from said venous reservoir holder by loading it from a direction above said venous reservoir holder.
55. A venous reservoir for extracorporeal circuits as claimed in claim 51 which is further adapted to be used in an operating room wherein connections between said inlet tube, said outlet tube, and said purge port and said extracorporeal circuit are made by an end user from above said venous reservoir thereby simplifying said connections in the operating room.
56. A venous reservoir for extracorporeal circuits as claimed in claim 51 wherein said supporting plate and said venous reservoir holder further prevents said venous reservoir from pulling out of, or twisting within, said venous reservoir holder.
57. A venous reservoir for extracorporeal circuits as claimed in claim 50 wherein said supporting plate further includes perfusion connectors for said inlet and outlet tubes and a luer connector for said purge tube, each of said connectors having an external end and an internal end, said external ends extending beyond said supporting plate facing away from said blood chamber, and said internal ends connected to said inlet, said outlet, and said purge tubes of said reservoir respectively.
58. A venous reservoir for extracorporeal circuits as claimed in claim 50, wherein said supporting plate further defines a second perimeter for said first planar surface that is larger than a third perimeter defined by said reservoir.
59. A vacuum assisted venous drainage system, said system comprising:
  - (a) a rigid container, said rigid container having
    - (i) a continuous vertical wall sealed to a bottom to create an internal chamber having an effective diameter;
    - (ii) a top opening for said container, said top opening having a first perimeter;
    - (iii) a vacuum port in fluid communication with said internal chamber of said container;
  - (b) and a disposable venous reservoir, said venous reservoir having:
    - (i) at least two walls, said walls sealed to form a blood chamber, at least one of said walls being flexible, said flexible wall having a blood side and an external side, said blood chamber having a top and a bottom;
    - (ii) an inlet tube for communication between an extracorporeal circuit and said blood chamber, said inlet tube having an inlet and an outlet, said outlet of said inlet tube ending in said blood chamber,

- (iii) an outlet tube, said outlet tube having an inlet and an outlet, said outlet tube extending from said bottom of said blood chamber to said extracorporeal circuit;
- (iv) a gas purge tube allowing the removal of gas from said blood chamber;
- (v) a supporting plate, said plate having a second perimeter, with said second perimeter larger than said first perimeter defined by the top opening of said container, said top opening of said container allowing a user to insert said venous reservoir within said container, said supporting plate closing the top opening of said container to form a closed housing for said blood chamber;
- (vi) said inlet, outlet, and a gas purge tubing sealed to and extending through said supporting plate;

wherein said vacuum, applied to said vacuum port of said container, is applied to said external side of, and is transferred to, said blood side of said flexible wall of said blood chamber thereby providing enhanced venous drainage.

- 60. A disposable venous reservoir as claimed in claim 59 wherein said disposable reservoir further includes a screen positioned across the blood flow path between the outlet of said inlet tube and the inlet of said blood outlet tube, said screen having a pore size of between about 40 microns to 150 microns.
- 61. A vacuum assisted venous drainage system as claimed in claim 59 wherein the disposable reservoir further includes said inlet tube entering said blood chamber at a first top corner at the top of said blood chamber and the outlet of said inlet tube positioned in said blood chamber diagonally across from said first top corner.
- 62. A vacuum assisted venous drainage system as claimed in claim 59 wherein said top opening of said container further includes a sealing means to provide a seal between said top of said container and said supporting plate of said reservoir to seal said blood chamber within said housing.
- 63. A venous reservoir as claimed in claim 59 wherein said supporting plate seals said blood chamber within said rigid housing when vacuum assisted venous drainage is used.
- 64. A venous reservoir for vacuum assisted venous drainage as claimed in claim 59 wherein said supporting plate is further used to support said venous reservoir as well as to, seal said housing when vacuum is applied to said vacuum port.
- 65. A vacuum assisted venous drainage system as claimed in claim 59 wherein said sealing means between said top opening and said supporting plate is further formed along a single plane.
- 66. A vacuum assisted venous system as claimed in claim 59 wherein said supporting plate is not secured to said ridged housing and relieves pressure relief when the pressure within said container is higher than atmospheric.
- 67. A vacuum assisted venous drainage system as claimed in claim 62 wherein gravity is used, at least partially, to initiate a seal by said sealing means.
- 68. A vacuum assisted venous drainage system as claimed in claim 59 wherein said container is non-disposable, and is sufficiently rigid to support an internal pressure of at least -200mmHg, said rigid container defining a cross sectional shape approximating the shape of the cross section of said venous reservoir when said blood chamber is full but not expanded beyond predefined limits.
- 69. A vacuum assisted venous drainage system as claimed in claim 59 wherein said container includes means to prevent the bottom of said venous reservoir from twisting within said rigid container.
- 70. A vacuum assisted venous drainage as claimed in 68 wherein said cross sectional shape of said rigid container is an ellipsoid.



71. A vacuum assisted venous drainage system as claimed in claim 59 wherein said continuous wall of said container includes a door sealable by an end user, allowing said user to access said venous reservoir within said container without removing said venous reservoir from said container.
72. A venous reservoir for vacuum assisted venous drainage as claimed in claim 71 wherein gravity is used, at least partially, to initiate a seal by said sealable door.
73. A vacuum assisted venous drainage system as claimed in claim 59 wherein said disposable venous reservoir includes sterile blood contacting surfaces, wherein said venous reservoir can be sealed within said rigid container by an end user without breaking the sterility of said blood contacting surfaces of said venous reservoir.
74. A vacuum assisted venous drainage system as claimed in claim 59 wherein at least a portion of said continuous vertical wall of said rigid container is transparent.
75. A vacuum assisted venous drainage system as claimed in claim 59 wherein said rigid container further includes at least one supporting means that enables an end user to attach said container to a heart lung machine of said extracorporeal circuit.
76. A vacuum assisted venous drainage system as claimed in claim 59 wherein said venous reservoir may be used for either gravity drainage or vacuum assisted drainage procedures.
77. A vacuum assisted venous drainage system for an extracorporeal circuit, said system comprising:
  - (a) A rigid sealable container for vacuum assisted drainage said container having:
    - (i) continuous vertical walls, a bottom, and a top forming an internal space;
    - (ii) a vacuum port in fluid communication with said internal space of said container;
    - (iii) an opening in said container having a first perimeter and
  - (b) a sterile venous reservoir, said venous reservoir having:
    - (i) at least two walls, at least one of said walls being flexible, said walls sealed to form a blood chamber, said blood chamber having a top and a bottom;
    - (ii) an inlet tube for communication between said extracorporeal circuit and said blood chamber, said inlet tube having an inlet and an outlet, said inlet tube entering the blood chamber from said top of said blood chamber, the outlet said inlet tube ending in said blood chamber;
    - (iii) an outlet tube, said outlet tube having an inlet and an outlet, said outlet tube extending from the bottom of said blood chamber to said extracorporeal circuit;
    - (iv) a gas purge tube allowing the removal of gas from said blood chamber;
    - (v) at least one sealing structure having a second perimeter, said sealing structure having an interior side facing said blood chamber, and an exterior side, said inlet, said outlet, and said gas purge tubes extending from said blood chamber through said sealing structure, to extend beyond said exterior side of sealing structure; said second perimeter of said sealing structure, being larger than said first perimeter of said opening, said sealing structure and said sealing container providing a sealed housing for said blood chamber;wherein an end user may seal the blood chamber within said rigid container without breaking the sterility of said venous reservoir.
78. A disposable venous reservoir for extracorporeal circuits, said reservoir comprising:
  - (a) at least two walls, with at least one of said walls being flexible, said walls sealed to form a blood chamber, said chamber having a top and a bottom;

- (b) an inlet tube for communication between said extracorporeal circuit and said blood chamber, said inlet tube having an inlet and an outlet, said outlet of said inlet tube ending in said blood chamber;
  - (c) an outlet tube, said outlet tube having an inlet and an outlet, said outlet tube extending from the bottom of said blood chamber to said extracorporeal circuit;
  - (d) a gas purge tube allowing the removal of gas from said blood chamber and
  - (e) a supporting plate having a first and a second planar surfaces, with said first planar surface facing said blood chamber,
- wherein the inlet of said inlet tube, the outlet of said outlet tube, and said gas purge tubing are sealed to and extend through said supporting plate.
79. A disposable venous reservoir as claimed in claim 79 wherein said disposable reservoir further includes a screen positioned across the blood flow path between the outlet of said inlet tube and the inlet of said outlet tube, said screen having a pore size of between about 40 microns to 150 microns.
80. A venous reservoir for extracorporeal circuits, said venous reservoir comprising:
- (a) at least two walls, with at least one of said walls being flexible, , said walls sealed along a first perimeter to form a blood chamber, said chamber having a top, a bottom, a left side and a right side;
  - (b) an inlet tube, said inlet tube having:
    - (i) an inlet end, communicating with said extracorporeal circuit; and
    - (ii) an outlet end communicating with said blood chamber,
  - (c) an outlet tube, said outlet tube having:
    - (i) an inlet end, said inlet end communicating with the bottom of said blood chamber, and
    - (ii) an outlet end, said outlet end communicating with said extracorporeal circuit; and
  - (d) a gas purge tube, said gas purge tube utilized to remove air bubbles from said blood chamber, said purge tube having:
    - (i) a blood chamber end; and
    - (ii) an external end for removal of said air bubbles,
- wherein the inlet end of said inlet tube, the outlet end of said outlet tube and the external end of said purge tube all extend in the same direction beyond said first perimeter.
81. A venous reservoir for extracorporeal circuits as claimed in claim 80 wherein said extension is less than 5" from said first perimeter of said blood chamber.
82. A venous reservoir as claimed in claim 80 wherein said outlet tube extends upward between said right and left sides above the top of said blood chamber.
83. A disposable venous reservoir for extracorporeal circuits, said reservoir comprising:
- (a) at least two opposing walls, with at least one of said walls being flexible, said walls sealed along said first perimeter to form a blood chamber, said chamber having a top and a bottom;
  - (b) an inlet tube having an inlet and an outlet, the inlet of said inlet tube in fluid communication with said extracorporeal circuit and the outlet of said inlet tube ending in said blood chamber;
  - (c) an outlet tube, said outlet tube having an inlet and an outlet, said outlet tube extending from the bottom of said blood chamber with the outlet of said outlet tube in fluid communication with said extracorporeal circuit;

- (d) a gas purge tube having an inlet and an outlet, said inlet of said purge tube extending downward from the top of said blood chamber to at least 50% of the vertical distance between said top and said bottom of said blood chamber;

wherein said purge tube prevents said at least one flexible wall from complete collapse against its opposing wall when said blood chamber is at least partially empty thereby allowing a more efficient removal of gas from said blood chamber.

84. A venous reservoir as claimed in claim 83 which further includes intermediate gas purge tubes that extend from the top of said blood chamber downward to at least 40% of the vertical distance between said top and said bottom of said blood chamber said intermediate gas purge tubes further increasing air removal efficiency.

85. A venous reservoir as claimed in claim 84 which further includes a spacer along the top of said blood chamber said spacer preventing said at least one flexible wall from complete collapse against its opposing wall along the top of said blood chamber when said blood chamber is at least partially empty thereby allowing a more efficient removal of gas from said blood chamber.

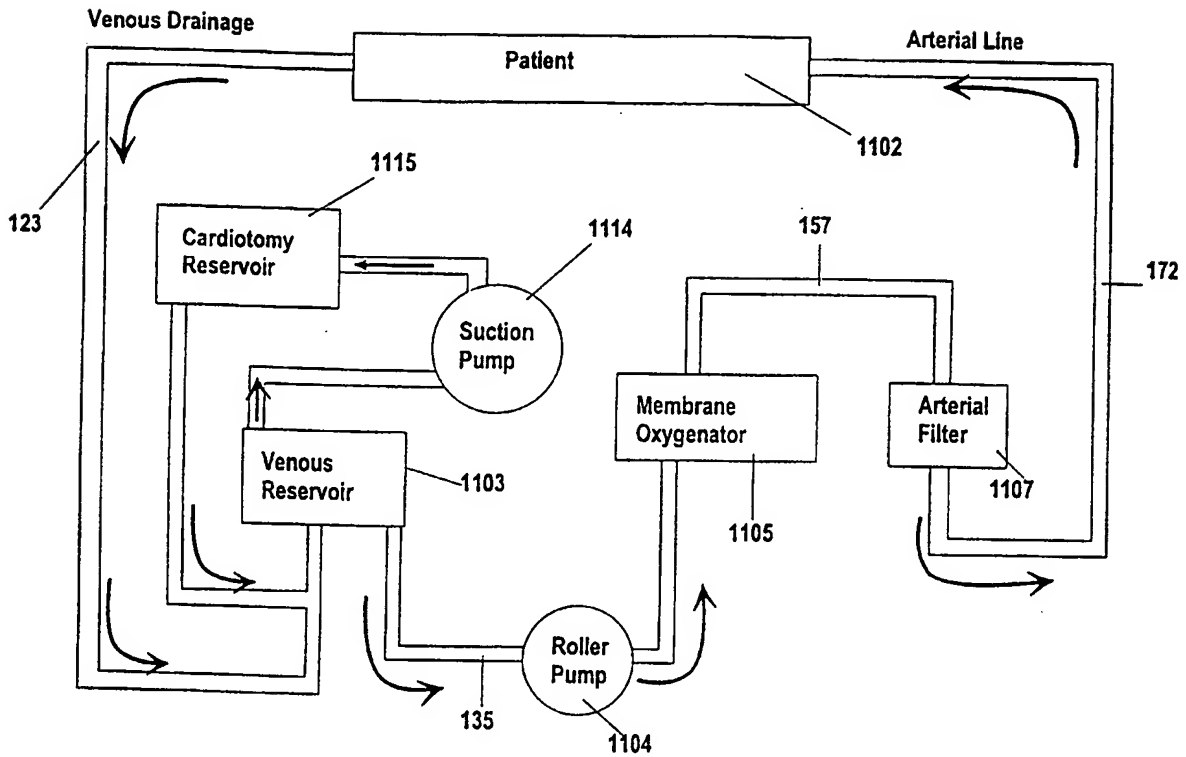
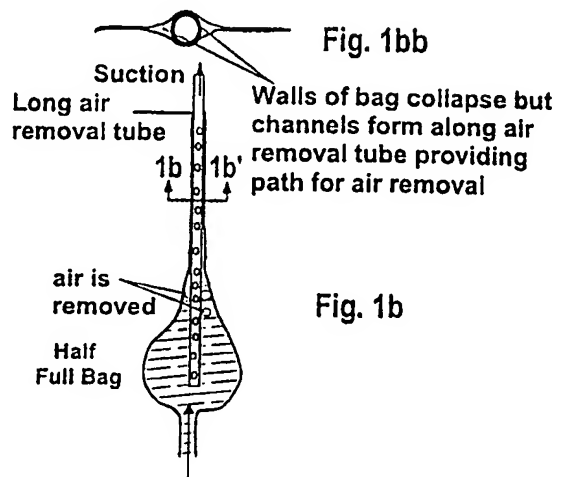
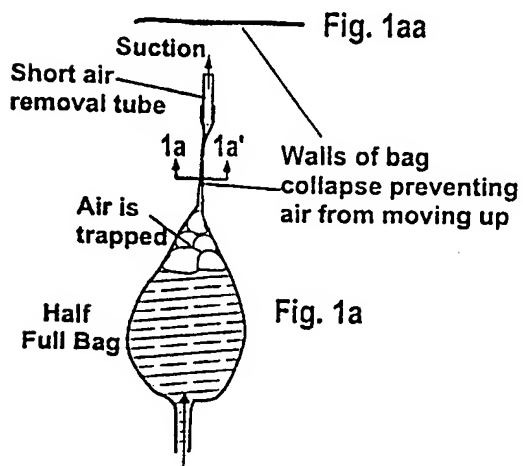
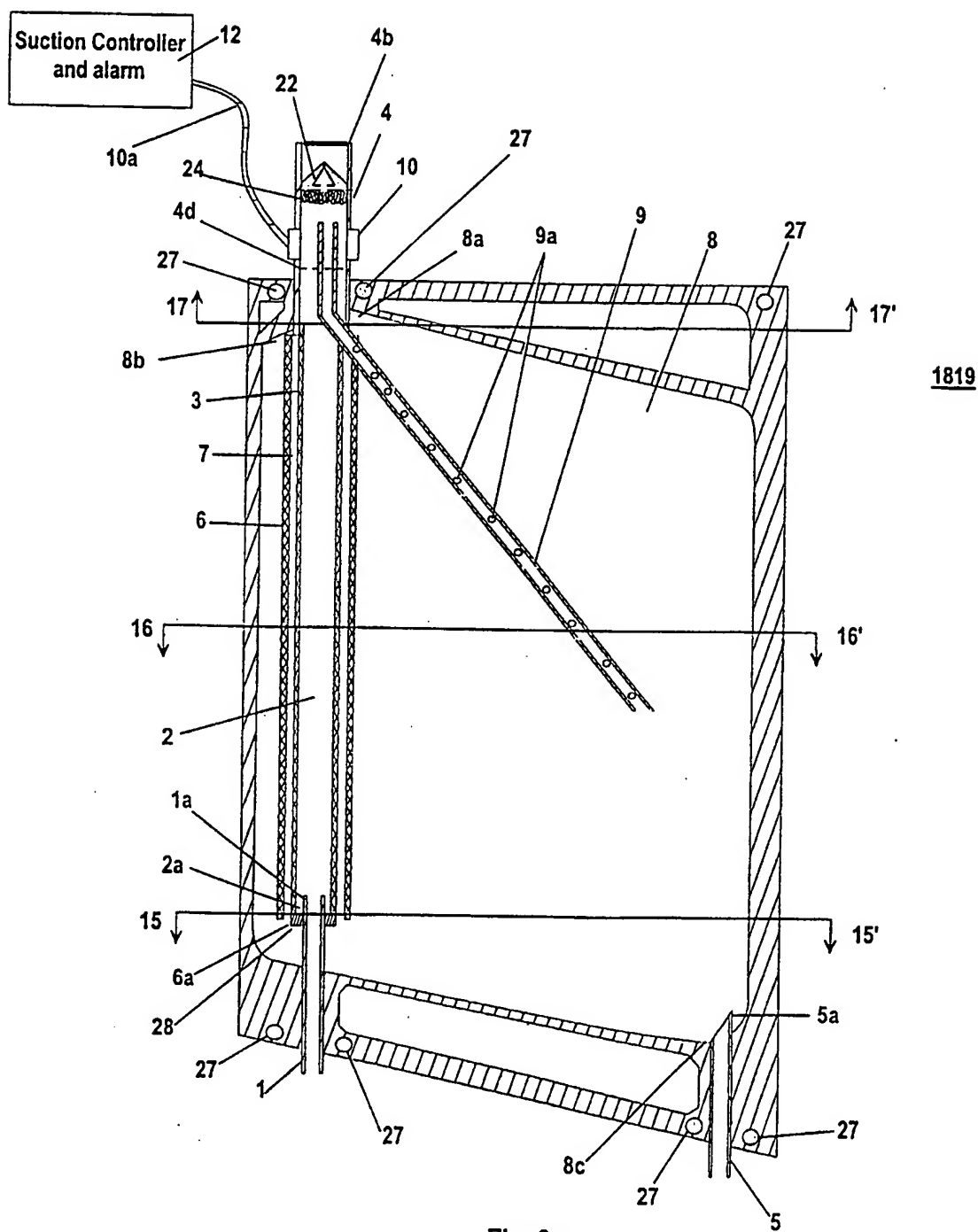
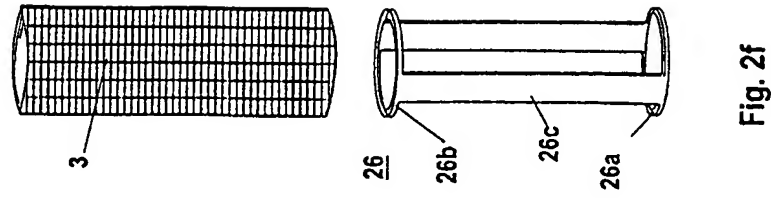
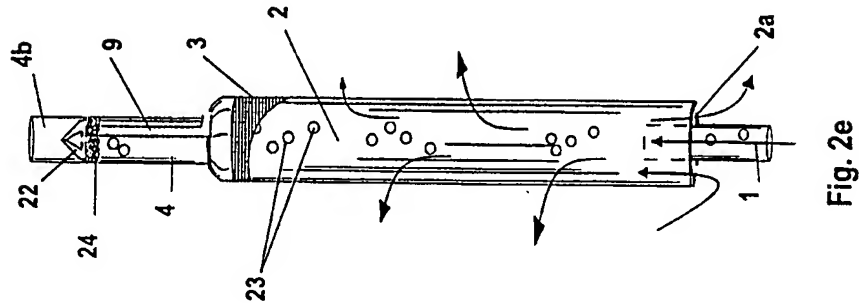
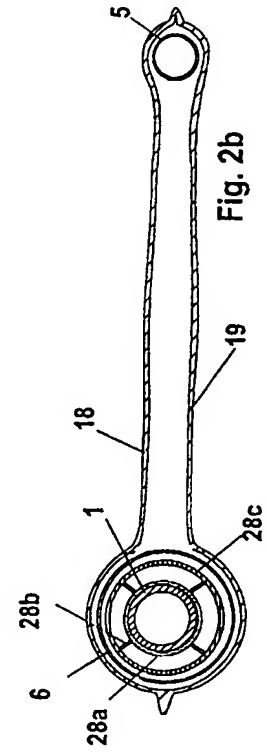
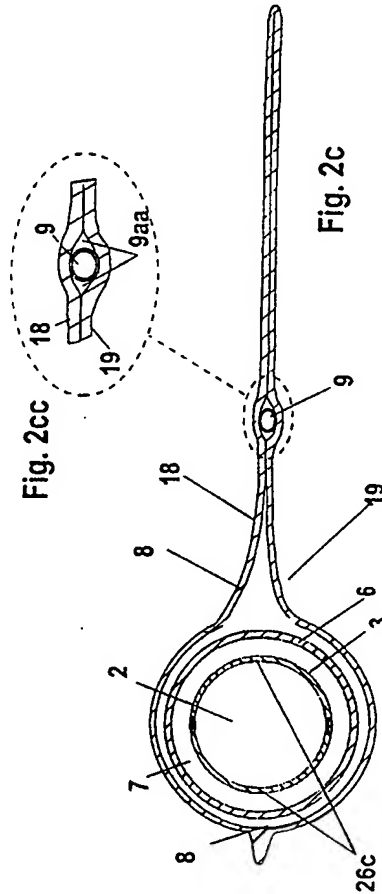
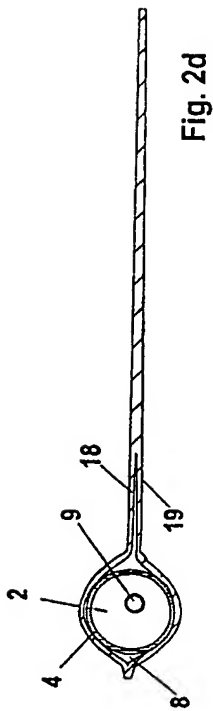


Fig. 1







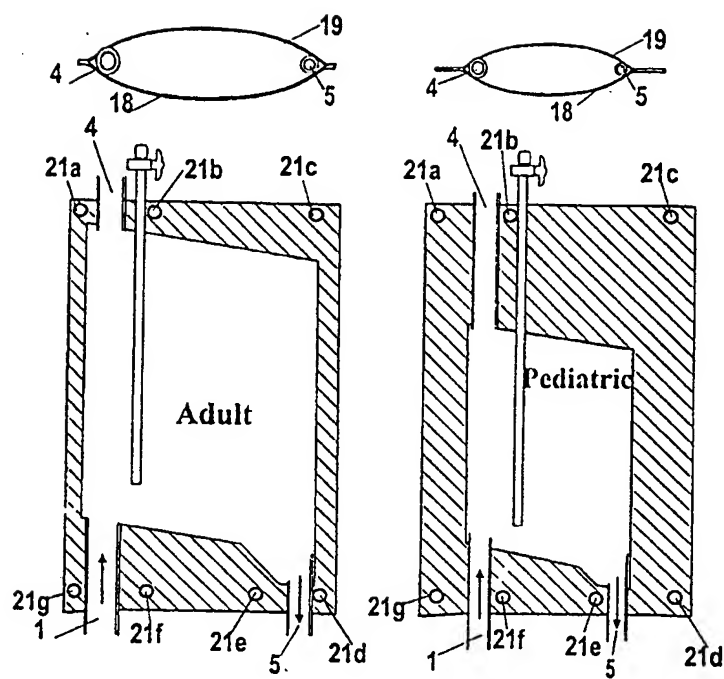
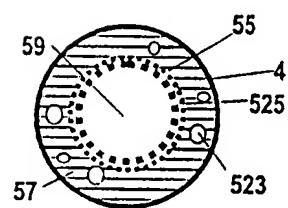
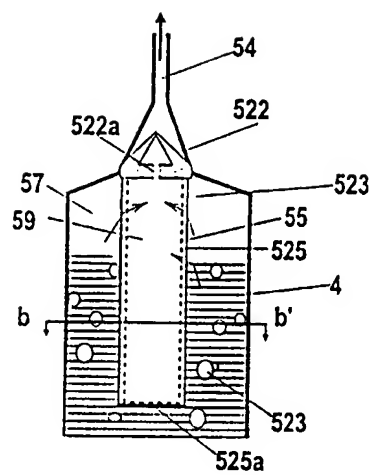
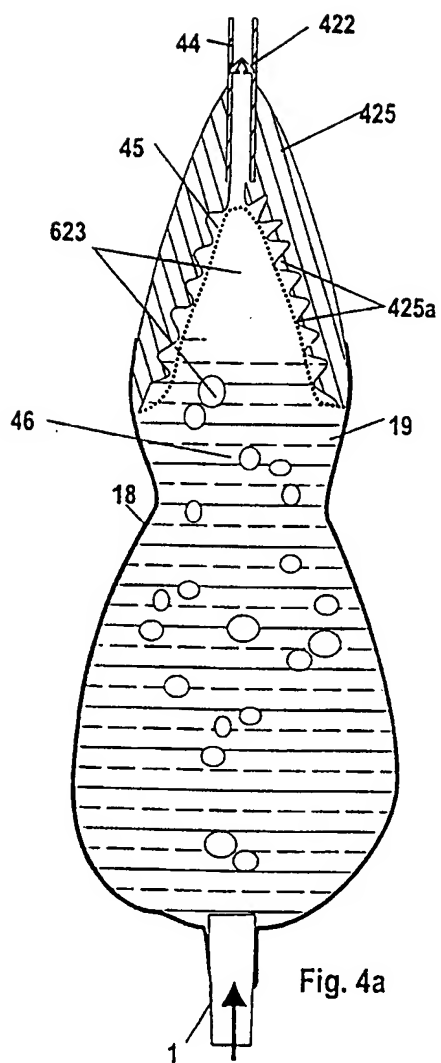


Fig. 3a

Fig. 3b





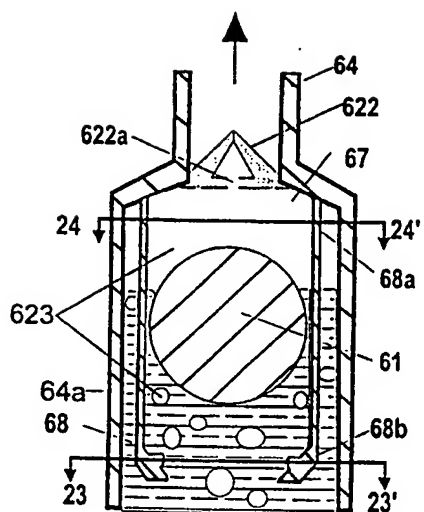


Fig. 6a

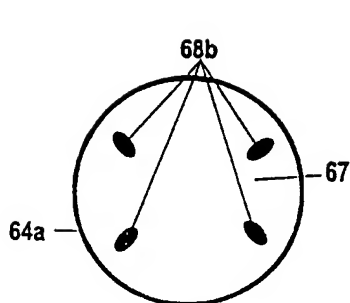


Fig. 6b

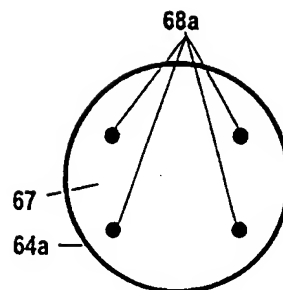


Fig. 6c

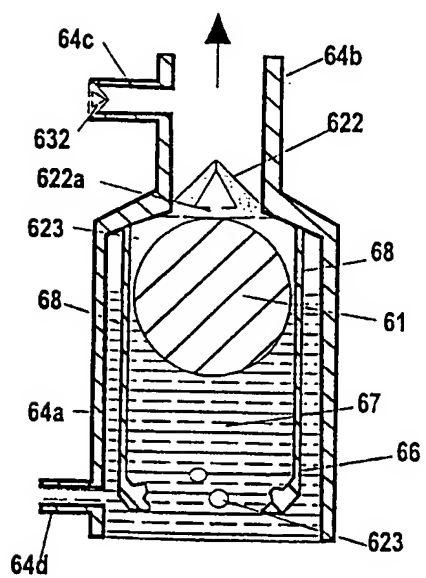
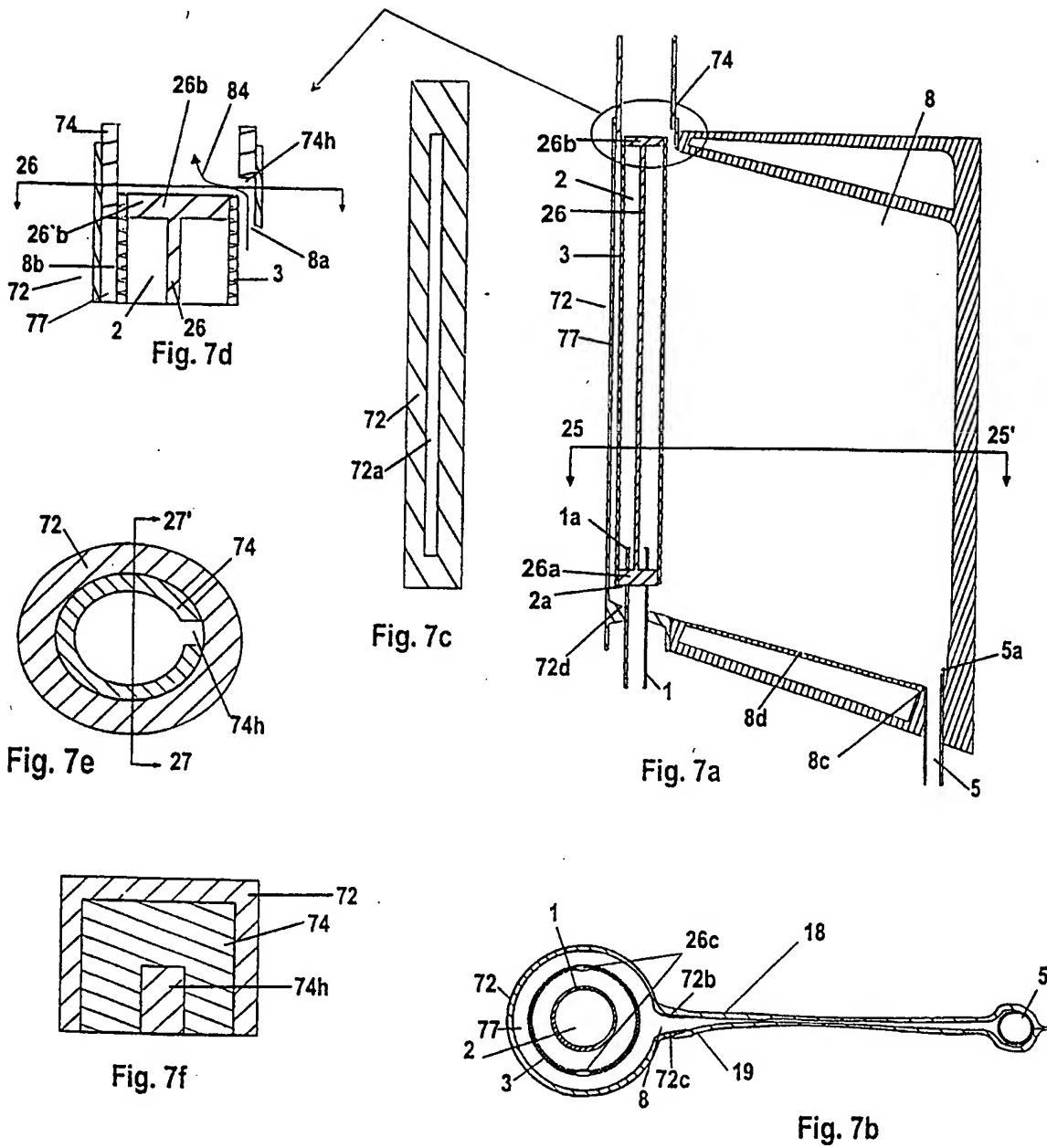


Fig. 6d



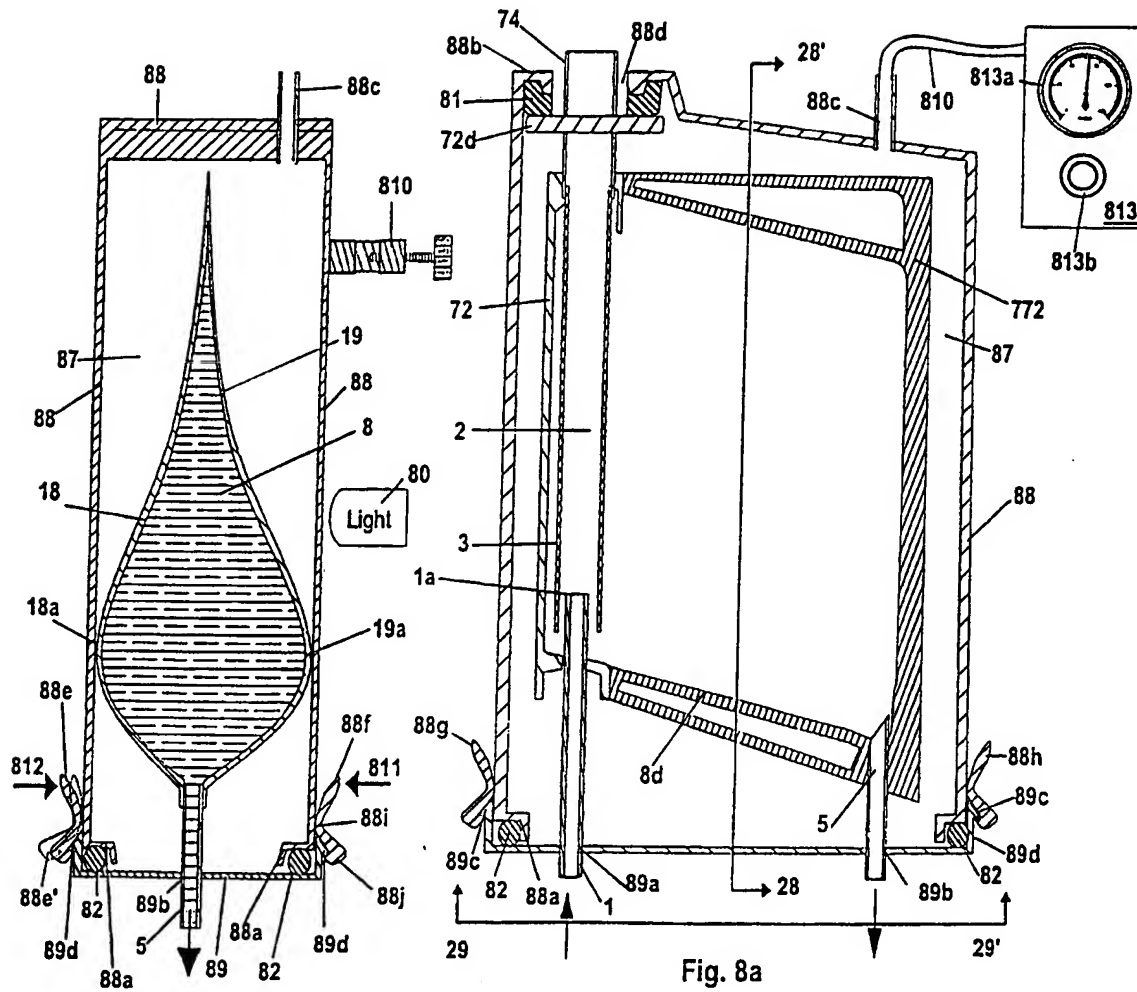


Fig. 8b

Fig. 8a

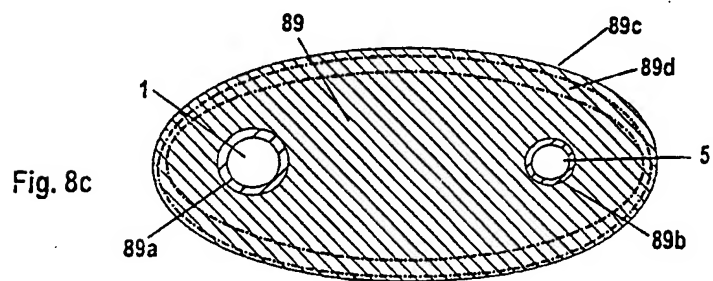
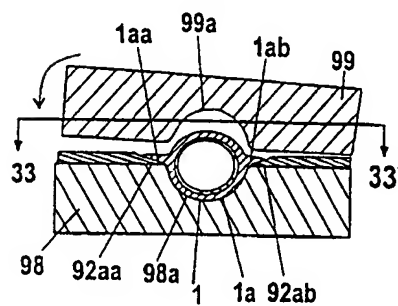
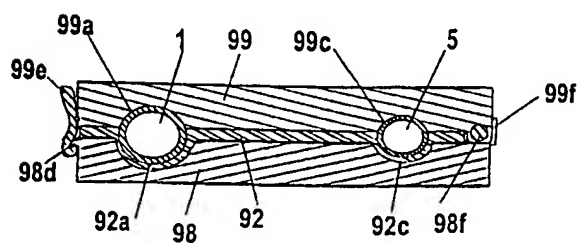
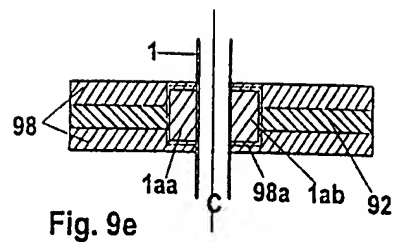
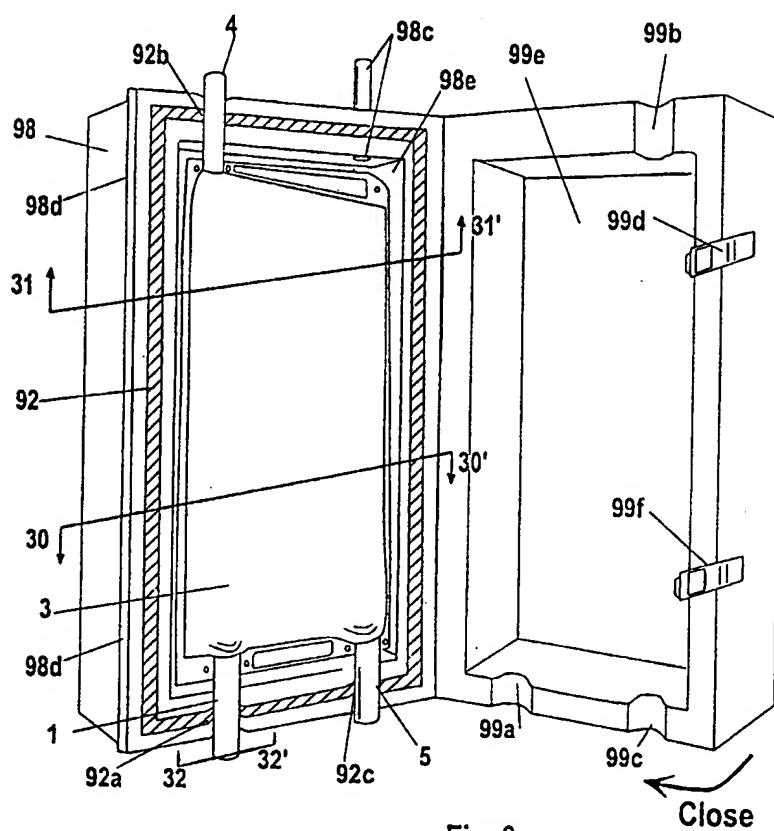
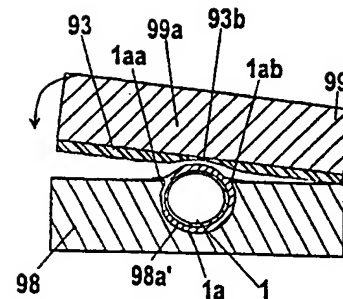
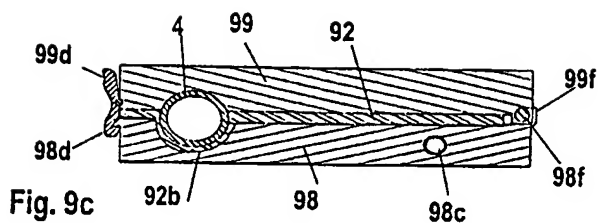
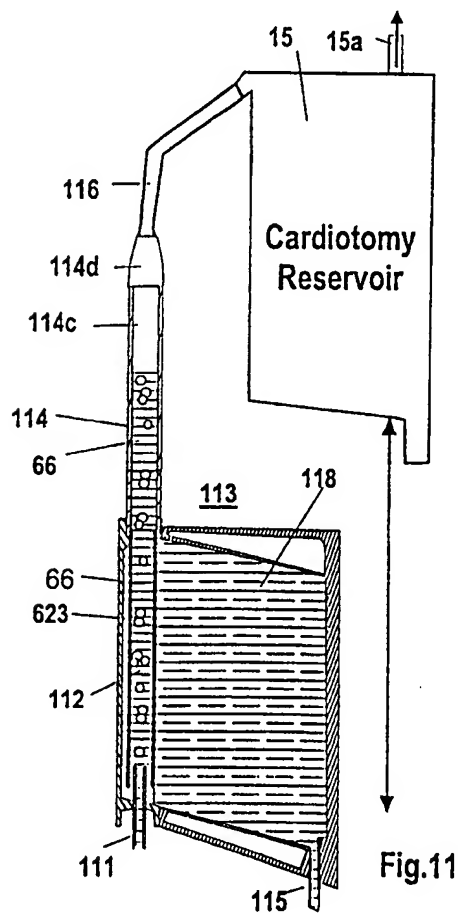
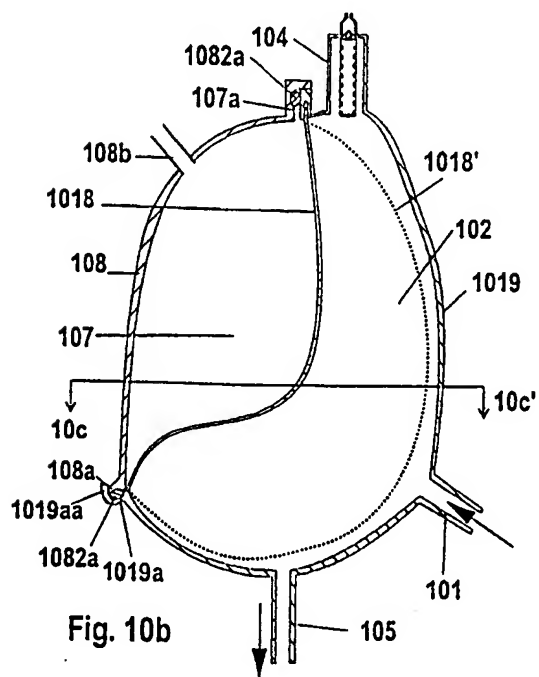
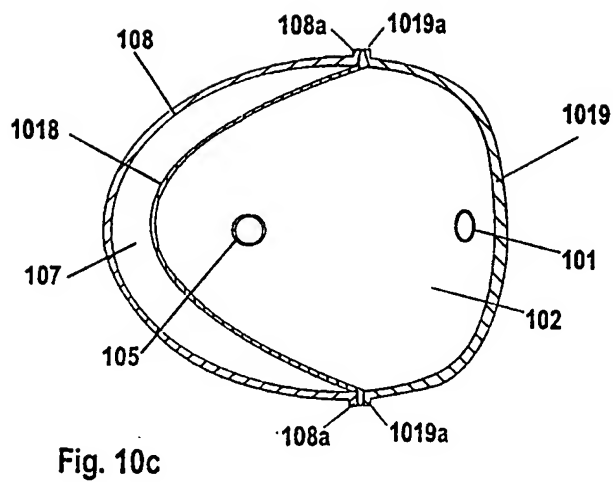
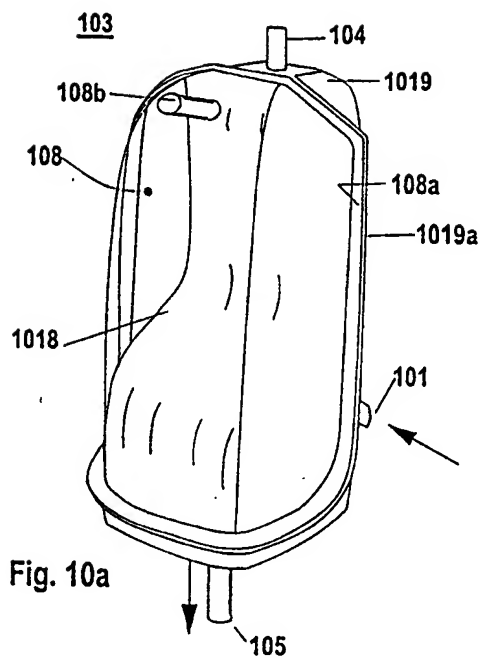
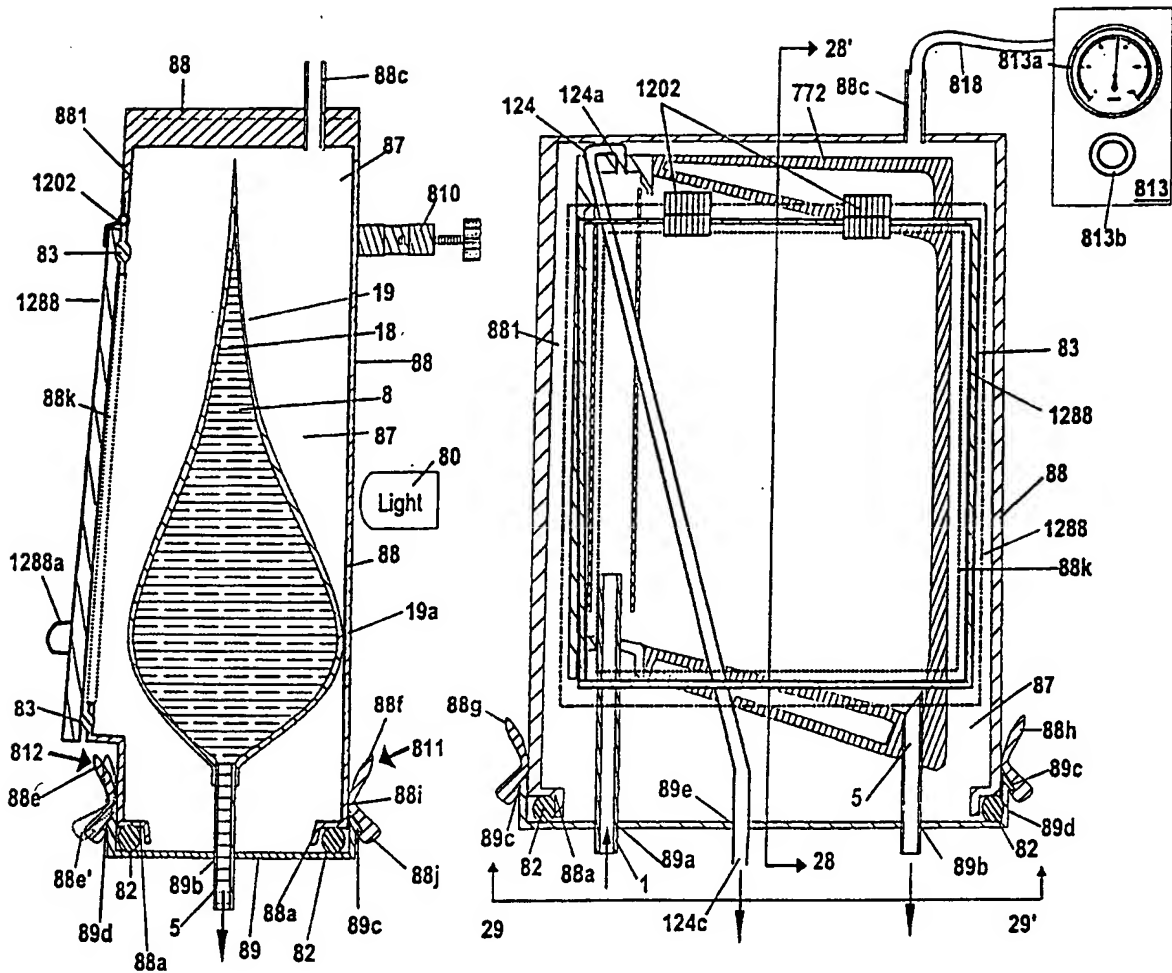


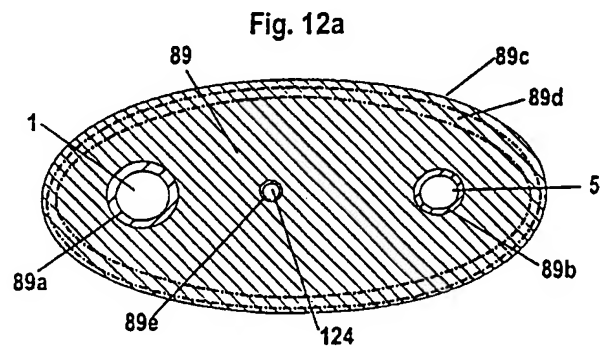
Fig. 8c



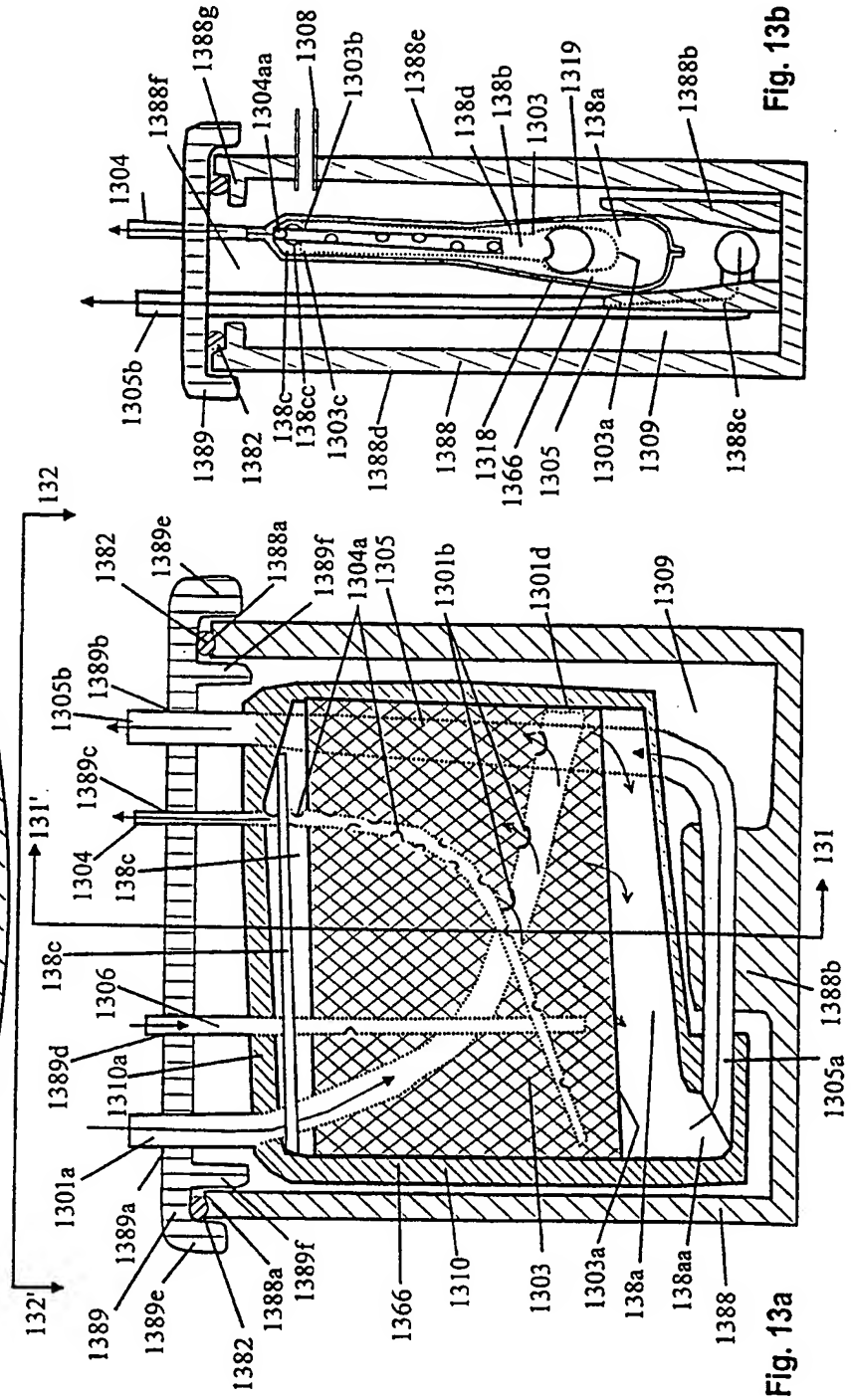
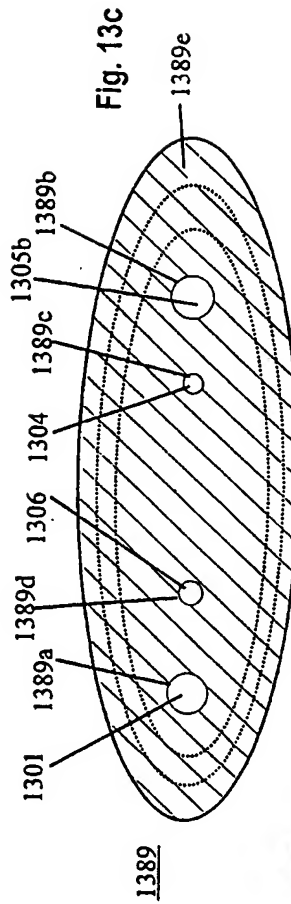


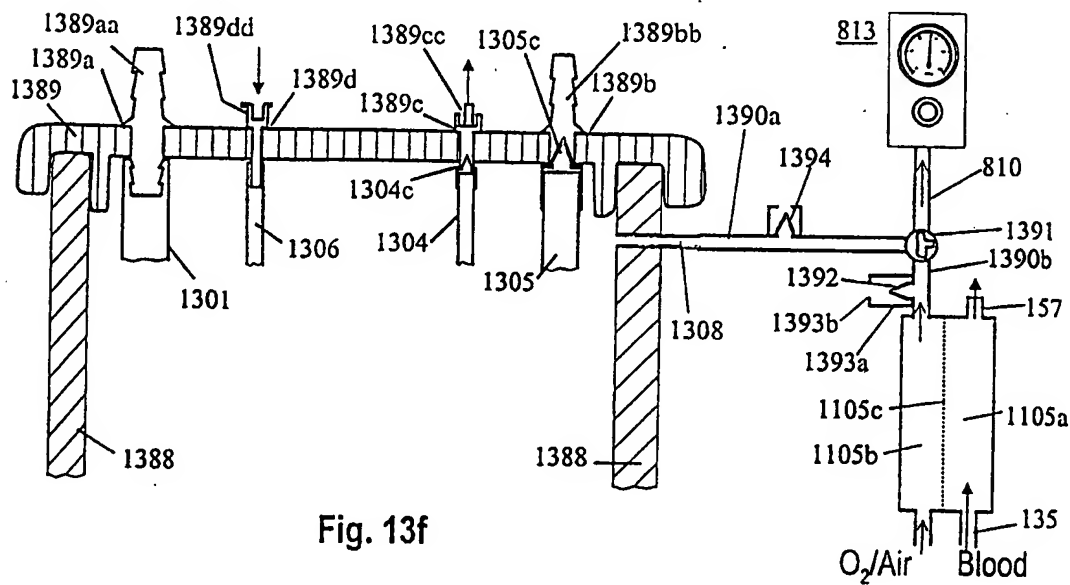
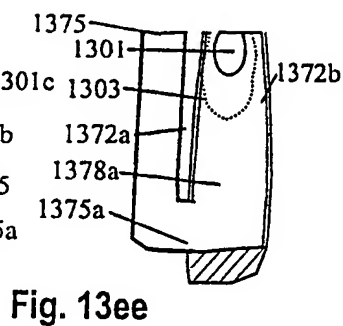
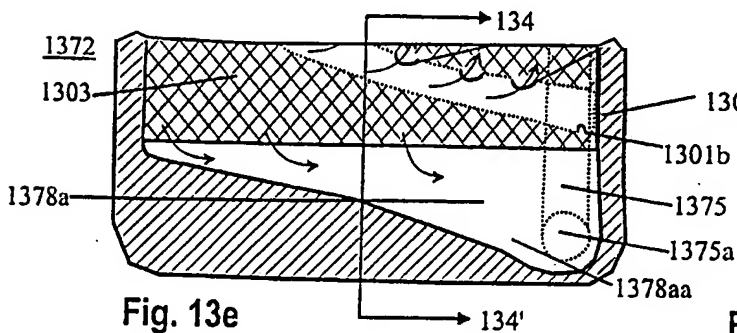
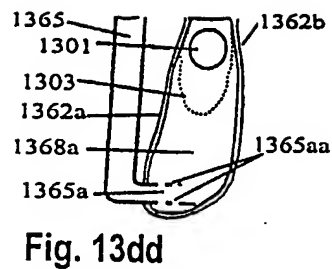
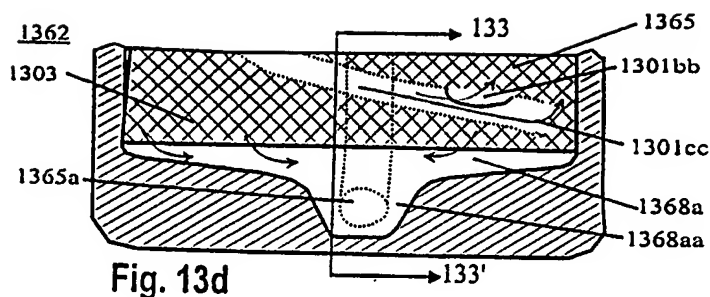


**Fig. 12b**



**Fig. 12a**







## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/19447

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 1/14, 37/00

US CL :422/45; 604/4

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 125/DIG. 3, DIG. 24; 210/256; 422/44-47; 604/4, 5, 317, 318, 322-324, 327, 403, 404, 408-410

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

Search Terms: venous reservoir, negative pressure, vacuum assisted venous drainage

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category*     | Citation of document, with indication, where appropriate, of the relevant passages                   | Relevant to claim No.   |
|---------------|--|---|
| X             | US 5,061,236 A (SUTHERLAND et al.), 29 October 1991, entire document.                                | 10  |
| X<br>---<br>Y | US 5,573,526 A (HESS) 12 November 1996, entire document.   | 1, 2, 4, 8, 10, 14-18, 20, 22, 39-42, 44, 46, 49-58, 78-82<br>-----<br>11-13, 83-85 |
| A             | US 4,705,497 A (SHITAOKOSHI et al.) 10 November 1987, Figs. 2-6, col. 2, line 65 to col. 7, line 24. | 1-85  |
| A             | US 5,693,039 A (STEWART et al.) 02 December 1997, entire document.                                   | 1-83  |

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

|   |  |
|---|--|
| * Special categories of cited documents:  | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| *A* document defining the general state of the art which is not considered to be of particular relevance  | *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| *E* earlier document published on or after the international filing date  | *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | *G* document member of the same patent family  |
| *O* document referring to an oral disclosure, use, exhibition or other means  |  |
| *P* document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search

07 NOVEMBER 1999

Date of mailing of the international search report

10 DEC 1999

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
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Authorized officer

PATRICIA BLANCO

Telephone No. (703) 305-1482

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/19447

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 6, 7, 9  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/19447

| C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT |   |                       |
|---|---|-----------------------|
| Category*   | Citation of document, with indication, where appropriate, of the relevant passages                  | Relevant to claim No. |
| A, P  | US 5,849,186 A (RANERI et al.) 15 December 1998, col. 3, line 40 to col. 7, line 30, and Figs. 2-4. | 1-83                  |
| A, P  | US 5,935,093 A (ELGAS et al.) 10 August 1999, entire document.                                      | 1-83                  |